

Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

08/03/2000

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Disclaimer: The information contained in these reports has not been scientifically or otherwise verified as to a cause and effect relationship and cannot be used to estimate the incidence of adverse drug reactions.

Adverse Event Reporting System (AERS) Office of Postmarketing Drug Risk Assessment Brief Description with Caveats of System October 18, 1999

IMPORTANT INFORMATION:

The Adverse Event Reporting System (AERS) in the Office of Postmarketing Drug Risk Assessment (OPDRA), was implemented to take advantage of up-to-date methods for data entry and database design. AERS contains all reports received since November 1, 1997.

BACKGROUND:

The AERS database is a computerized system for storing adverse events reported by health professionals and others. The system contains adverse events detected and reported after marketing of the drug.

AERS relies on health professional to detect new clinical events, to attribute the appearance of the clinical event to the administration of a drug, and to report that clinical event.

The health professional may choose to report the adverse reaction to the FDA or to a drug firm, who must, by law, report to the FDA. Ninety percent of the FDA's reports are received from drug manufacturers. OPDRA receives the remaining ten percent directly from other reporters. (i.e., Health Professionals and consumers).

Data from all reports are entered into AERS and the report images are scanned into an Electronic Filing System (EFS). All reports are retrieved by accessing the Individual Safety Report (ISR) number.

Copies of individual case safety reports, which are summarized in this printout, may be obtained by submitting a separate FOI request. When requests are submitted for copies of report images, the ISR number should be listed in tabular-format in ascending order as shown in the following example:

ISR NUMBER

3000913-1 3000917-9 3001581-5

There is a \$29.00/Hour search time and a \$.50/page charge. Please note that there will be redactions made to all personal identifiers on the report.

Definitions of the FOI R

Date Date the report was received by the FDA.

ISR Number Unique number for identifying an AERS report.

Report Type The type of ISR received. Expedited (15-day) and

periodic reports are from manufacturers; "direct" reports are voluntarily submitted to the FDA by non-

manufacturers.

Report Type Description

Expedited (15-day) Mandatory reports received from the manufacturer

informing the FDA of adverse events that are both serious and unexpected. By law, these reports must be delivered to the FDA, within 15 calendar days of

the initial receipt by the manufacturer.

Periodic These are mandatory reports that do not fall into the

expedited category. These reports are delivered

quarterly to the FDA.

Direct These reports are from health professionals, private

individuals or sources other than manufacturers.

Company Report Number Manufacturer's unique report identifier.

Age Numeric value of patient's age at event. 🕝

Gender The gender of the patient (male, female, unknown, or

Not specified).

Outcome The results of the adverse event as. The following

events are potential choices.

Outcome **DESCRIPTION**

DE Death LT Life-Threatening

НО Hospitalization - Initial or Prolonged DS

Disability

CA Congenital Anomaly

RI Required Intervention to prevent permanent

impairment/damage

OT Other PT (Preferred Term)

The reported reaction, in medical terminology,

describing the event. This is coded using the Medical

Dictionary for Regulatory Activities (MedDRA).

Report Source

Identifies the initial source of the report. (I.e., Health

Professional, Consumer, etc..)

Product

Name of drug.

Role

S = Suspect

C = Concomitant PS = Primary Suspect

SS = Secondary Suspect

*Suspect Drug

The drug that the initial reporter deemed most likely to

be associated with the reactions.

Concomitant Drug

A list of any drugs taken at the same time as the

suspect medication, but not suspected of causing the

adverse event.

Manufacturer

The company that manufacturers the drug.

Route

Route of administration of the drug.

Dose

Quantity of drug administered in a 24-hour period.

Units

Modifies the dose with units of measurements (e.g.,

mg, IU, ml, etc.).

Duration

Number of days the drug was used.

CAVEATS:

There are some important things to remember when reviewing or analyzing data from AERS.

- Reports contain only those reactions voluntarily submitted either directly to the FDA or to the drug manufacturer by consumers and/or members of the health profession and which have been entered into the AERS computerized filing system since November 1,1997.
- The information contained in the reports has not been scientifically or otherwise verified.
- 3. For any given report, there is no certainty that the suspected drug caused the reaction. This is because physicians are encouraged to report suspected reactions. The event may have been related to the underlying disease for which the drug was given to concurrent drugs being taken or may have occurred by chance at the same time the suspected drug was taken.
- Accumulated case reports cannot be used to calculate incidence or estimates of drug risk.
- Numbers from these data must be carefully interpreted as reporting rates and not occurrence rates. True incidence rates cannot be determined from this database. Comparisons of drugs cannot be made from these data

				Ofinterwateri		Maria III			
Date: 11/04/1983	ISR Number: 154121-2	Report Type: Expedited							
Outcome	РТ		(13-Day)	Company Report Number:	MS8366	51	Age: 15 YR	Ger	ider: Female
Outcome	Depression Nec	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
			Accutane		PS	Roche	ORAL.		26
Date: 03/09/1983	ISR Number: 157641-X	Report Type: Expedited	(15-Day)	Company Report Number:	MS8398		Age: 25 YR		ıder: Female
Outcome	PT	Report Source	Product				•	Ge	tuer: remate
Other	Palpitations		Accutane		Role PS	Manufacturer	Route	Dose/Unit	Duration
			·		15	Roche	ORAL		
Date: 03/09/1983	ISR Number: 157646-9	Report Type: Expedited	(15-Day)	Company Report Number:	00MS83	184	Age: 19 YR	Ger	ıder: Female
Outcome	PT	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Amnesia Nec Hepatic Function Abnormal Nos		Accutane		PS	Roche	ORAL	2000 Outt	105
	Jaundice Nos								103
	Weight Decreased	-							
Date: 04/14/1983	ISR Number: 158987-1	Report Type: Expedited	(15-Day)	Company Report Number:	MS83-2	12	Age: 13 YR	Ger	ıder: Male
Outcome	PT	Report Source	Product	,	Role	Manufacturer	704.		
Other	Emotional Disturbance Nos		Accutane		PS	Roche	Route	Dose/Unit	Duration
	Hyperkinetic Syndrome		Depakene		C .	TOTAL	ORAL ORAL		153
			Tegretol	1	С		ORAL		•
Date: 05/13/1983	ISR Number: 161749-2	Report Type: Direct		Company Report Number:			· · · · · · · · · · · · · · · · · · ·		
Outcome	PT	Report Source	D34	• •		•	Age: 42 YR	Gen	ider: Male
	Coordination Abnormal Nos	Report Source	Product Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
	Nervousness		Accutane	1	PS	Roche	-ORAL		
	Tachycardia Nos Tremor Nec								
Date: 06/16/1983	ISR Number: 164688-6	D							
		Report Type: Expedited	(15-Day)	Company Report Number:	00MS83	35	Age: 17 YR	Gen	der: Female
Outcome Other	Emotional Disturbance Nos	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	The state of the s		Accutane	;	PS	Roche	ORAL		
Date: 06/16/1983	ISR Number: 164689-8	Report Type: Expedited	(15-Day)	Company Report Number:	0MS833	36			
Ontcome	PT	Report Source	Product				Age: 16 YR	Gen	der: Male
Other	Asthenia				Role	Manufacturer	Route	Dose/Unit	Duration
	Depression Nec Personality Disorder Nos		Accutane	1	PS	Roche	ORAL		

		FLA		Lean Region							
		Sec. Sec.		Of information		A COROLL					
Date: 06/16/1983	ISR Number: 164690-4	Report Type: Expedited (15-Day)	Company Report Number	r: 0MS83	291	Age:	21 YR	Ge	nder: Male	
Outcome	<u>PT</u>	Report Source	Product		Role	Manufactorer		_			
Other	Impotence		Accutane		PS	Roche		ule	Dose/Unit	Duration	_
					гэ	Roche	OF	AL.		120	
Date: 08/03/1983	ISR Number: 165237-9	Report Type: Periodic		Company Report Number	r: 0MS83	449	A 00:	17 YR			
Outcome	PT	Report Source	D	• •			rige.	17 IK	U a	nder: Femal	le
Hospitalization -	Amnesia Nec	Report Bourte	Product		Role	Manufacturer	Re	ute	Dose/Unit	Duration	
Initial or Prolonged	Benign Intracranial Hypertension Ecchymosis		Accutane		PS	Roche					_
Date: 12/02/1983	ISR Number: 172586-7	Report Type: Expedited (15-Day)	Company Report Number	r: MS836	78	Age:	38 YR	Ge	nder: Femal	 le
Outcome	<u>PT</u>	Report Source	Product		Role	Manufacturer	h.	ute			
	Asthma Nos		Accutane		PS	Roche			Dose/Unit	Duration	_
	Depression Nec		Апаргох		SS	Roche	OR	AL.		119	
	Myalgia Oesophagitis				33						
Date: 12/14/1983								_			
Date: 12/14/1903	ISR Number: 172587-9	Report Type: Expedited ((5-Day)	Company Report Number	: MS836	88	Age:	38 YR	Ge	nder: Fernal	
Outcome	PT	Report Source	Product					110	- Ga	nuer: remai	ie
Hospitalization -	Depression Nec				Role	Manufacturer	Ro	ute	Dose/Unit	Duration	_
Initial or Prolonged			Accutane		PS	Roche	OR	AL		41	•
Other			Lithium		C		OR	AL			
			Restoni		C	Sandoz	OR	AL			
Date: 12/13/1983	ISR Number: 172602-2	Report Type: Direct		Company Report Number		·					
Outcome	PT	B		T-V responsibility	•		Age:	20 YR	Ger	nder: Male	
Other	Depression Nec	Report Source	Product		Role	Manufacturer	Ro	nte	Dose/Unit	Duration	
		Health Professional	Accutane		PS	Roche	OR	AL	-,	95	-
Pate: 12/06/1983	ISR Number: 174700-6	Report Type: Periodic		Company Report Number	- MS8353	37		32 YR	Gen	ider: Female	
Outcome	<u>PT</u>	Report Source	Product		D.1				- Cui	remate	
Other	Headache Nos		Accutane		Role	Manufacturer	Ro	rte	Dose/Unit	Duration	_
	Insomnia Nec				PS	Roche	OR.	AL.		7	
	Nervousness		Erythromyci	n.	C		OR.	AL		28	
	Palpitations									-	
Date: 02/01/1984	ISR Number: 176897-0	Report Type: Direct		Company Report Number	: 0000000	00	Age:	30 YR	Gen	der: Female	
Outcome	_ <u>PT</u>	Report Source	Product		Role	Manufacturer					-
	Amenorthoea Nos	Consumer	Асситапе				Roi	ite	Dose/Unit	Duration	

				e Logni Rozovini Officiernation (
Date: 05/14/1984	ISR Number: 182736-4								
		Report Type: Periodic		Company Report Number:	MS8374.	5	Age: 30 YI	₹ Ger	ıder: Female
Outcome	PT Alopecia	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	
Omer	Cheilitis		Accotane		S	Roche	ORAL	Dose Ont	Duration
	Confusion		Parnate	C	:		ORAL		101
	Nail Disorder Nos						OKAL		
Date: 03/08/1984	ISR Number: 183567-1	Report Type: Expedited	(15-Day)				· · · · · · · · · · · · · · · · · · ·		
Outcome	PT		(10-Day)	Company Report Number:	MS8476		Age: 63 YF	₹ Ger	ider: Male
Other	Depression Nec	Report Source	Product	<u>P</u>	lole	Manufacturer	Route	Dose/Unit	Duration
	Sedation		Accutane	P	S	Roche	ORAL		54
Date: 05/18/1984	ISR Number: 184682-9	Report Type: Direct							
Outcome	PT			Company Report Number: (0000000	0	Age:	Gen	der: Unknown
	Impotence	Report Source	Product	R	ole	Manufacturer	Route	Dose/Unit	Duration
		Health Professional	Accutane	P	S	Roche	ORAL	<u> Dana Cint</u>	Direction
Date: 05/14/1984	ISR Number: 184683-0	Report Type: Expedited (15-Day)	Company Report Number: 1				-	
Outcome	PT		•	Company Report Number: 1	VI-58436		Age: 27 YF	C Gen	der: Male
Other	Impotence	Report Source	Product	<u>R</u>	ole	Manufacturer	Route	Dose/Unit	Duration
			Accutane	P	S	Roche	ORAL		118
Date: 06/21/1984	ISR Number: 184955-X	Report Type: Periodic		Company Report Number: 8	4102				
Outcome	PT	Report Source		rang responsitionaber, a	4172		Age: 37 YR	Gen	der: Female
	Depression Nec	Keport source	Product	<u>R</u>	<u>ole</u>	Manufacturer	Route	Dose/Unit	Duration
			Accutane	P	3	Roche	ORAL		120
Date: 07/10/1984	ISR Number: 186192-1	Report Type: Periodic		Company Report Number: 8	4260				
Outcome	PT	Report Source	.		4200		Age: 29 YR	Gen	der: Male
	Dysphonia	- Apple Soute	Product		ole	Manufacturer	Route	Dose/Unit	Duration
			Accutane	PS	3	Roche	ORAL		64
Date: 07/18/1984	ISR Number: 186519-0	Report Type: Periodic		Company Report Number: M	4584300				
Outcome	PT	Report Source	D 3- 4	Tank solver tradition; h	1004289		Age: 34 YR	Gen	der: Female
Other	Palpitations		Product	<u>R</u>	ole	Manufacturer	Route	Dose/Unit	Duration
	Syncope		Accutane	PS		Roche	ORAL		26
ate: 03/08/1984	ISR Number: 186549-9		Prednisone	c			ORAL		14
		Report Type: Expedited (1	5-Day)	Company Report Number: M	IS8496	,	Age: 18 YR	Gen	der: Malc
Outcome	PT	Report Source	Product	Re	J.	M	-		
Other	Depression Nec Weight Decreased		Accutane	PS		Manufacturer	Route	Dose/Unit	Duration
	rr eight Decreased			rs		Roche	ORAL		104

Product Product Report Source Product Role Rol	Date: 10/11/1984 Outcome	ISR Number: 301087-8	Report Type: Periodic		Company Report Numb	er: MS845	9	Age: 40 YR	Gen	der: Female
Date 1011/1984 18R Number: 301091-X Report Space Product Company Report Number: MS84525 Age 40 YR Gord-type Product Report Space Report Space Product Report Space Re	Oincome	Depression Nec	Report Source	Product		Role	Manufacturer	Route		
Date 1011/1094				Accutane		PS	Roche			
Outcome PT Report Searce Product Product PS Manufacturer Age: dots Outcome Does Unit Outcome Date: 10/26/1984 ISR Number: 3015/5-4 Report Type: Periodic Company Report Number: MS84572 Age: dots 32 YR Gut-tr Pomble: Does Unit Outcome PT Report Source Product Role Manufacturer Relat Does Unit Duration Date: 10/17/1984 ISR Number: 301997-1 Report Type: Periodic Company Report Number: MS84532 Age: dots 30 YR Gut-tr Pomble: Does Unit Date: 10/17/1984 ISR Number: 301997-1 Report Source Product Role Manufacturer Relat Does Unit Pomble: Does Unit	Date: 10/11/1984	ISR Number: 301091-X	Report Type: Periodic		G P 411					
Depression No.	Outcome	PT	·		Company Report Numb	er: MS8453	9	Age: 40 YR	Gen	der: Female
Part 1026/1984 15K Number: 3015754 Report Super Periodic Company Report Number: MS8457 Report Periodic Report Super Periodic Report Number: MS8457 Report Number: MS8457 Report Number: MS8458 Report Number: MS8			Report Source			Role	Manufacturer	Route	Dose/Unit	Duration
Date 10/26/1984 SR Namber; 301575-4 Report Type: Pariodic Company Report Number; MS84572 Age 32 YR Gender Pendale Date				Accutane		P\$	Roche	ORAL		
Outcome PT Repair Source Product Role Manufacturer Role Dose/Unit Description Date: 10/17/1984 ISR Number: 301997-1 Report Type: Periodic Company Report Number: MS84535 Age: 30 YR God-ter Female Outcome PT Report Source Product Role Manufacturer Role ORAL Description Description Date: 10/17/1984 ISR Number: 301997-1 Report Source Product Role Manufacturer Role ORAL Description Description Penale Obits: 10/17/1984 ISR Number: 301998-3 Report Type: Periodic Company Report Number: MS84533 Age: 31 YR God-tr Female Outcome PT Report Source Product Role Manufacturer Role Description Description Description Company Report Number: MS84572 Age: 32 YR God-tr Female Outcome PT Role Company Report Number: MS84572 Age: 32 YR God-tr Poult-tr Female Outcome <	Date: 10/26/1984	ISR Number: 301575-4	Report Type: Periodic		Company Beneri Numb	M0045				
Adaptagia Ada	Outcome	_ PT	Penant Same		company report (tumb	EF: 143043	2	Age: 32 YR	Gen	der: Female
Date: 10/17/1984 ISR Number: 301997-1 Report Type: Periodic Company Report Number: MS84535 Age: 30 YR Gender Pernale	_	Arthralgia	Keport Source			Role	Manufacturer	Route	Dose/Unit	Duration
Outcome PT Report Source Product Role Manufacturer Role Dose/Unit Duration Other Chest Pain Accutane PS Roche ORAL Image: Spring of the pain		Depression Nec		Accutane		PS	Roche	ORAL		126
Outcome PT Report Source Product Role Manufacturer Role Dose/Unit Dose/Unit Dutstion Other Closs Pain Accutane PS Roche ORAL Image: Section of the content o	Date: 10/17/1984	ISR Number: 301997-1	Report Type: Periodic		Company Report Number	er: MS8453	5	Agai 20 VD		
Other Cased Pain Accutane Role Manufacturer Role ORAL Dose/Unit Durstion Palpitations Factlycardia Nos Accutane PS Roche ORAL VIII. Syntex ORAL VIII. Female Palpitations Accutane PS Roche ORAL VIII. Product Syntex ORAL VIII. Product Syntex ORAL VIII. Product Name Product Report Source Product Roche Manufacturer Roche ORAL VIII. 100e/Unit Dose/Unit Durstion Obte: 10/23/1984 ISR Number: 302664-0 Report Type: Periodic Company Report Number: Manufacturer Roche ORAL VIII. Dose/Unit Durstion Outcome PT Report Source Product Roche ORAL No Dose/Unit Durstion Outcome PT Report Source Product Roche Roche ORAL Dose/Unit Durstion	Outcome	<u>PT</u>	Report Source	Product				age. 50 IR	Gen	der: Female
Falphage	Other							Route	Dose/Unit	Duration
Date: 10/17/1984 ISR Number: 301998-3 Report Type: Periodic Company Report Number: MS84533 Age: 31 YR Gender: Female								ORAL		
Outcome PT Report Type: Periodic Company Report Number: MS84533	D-4 10/17/1994					_C	Syntex	ORAL		
Other Depression Nec Libido Decreased Product			Report Type: Periodic		Company Report Number	r: MS8453	3	Age: 31 YR	Gene	ler: Female
Libido Decreased			Report Source	Product		Pole	Manufactoria	ъ.		
Date: 10/23/1984 ISR Number: 302664-0 Report Type: Periodic Company Report Number: MS84572 Age: 32 YR Gender: Permale Outcome PT Report Source Product Role Manufacturer Route Dose/Unit Duration Date: 10/18/1984 ISR Number: 303215-7 Report Type: Periodic Company Report Number: MS84533 Age: 31 YR Gender: Pemale Outcome PT Report Source Product Role Manufacturer Route Dose/Unit Duration Cother Depression Nec Accutane PS Roche ORAL 1000000000000000000000000000000000000	Other			Accutane					Dose/Unit	
Outcome PT Report Type: Periodic Company Report Number: MS84572 Age: 32 YR Gender: Female Outcome PT Report Source Product Role Manufacturer Route Dose/Unit Duration Accutance PS Roche ORAL 126 Date: 10/18/1984 ISR Number: 303215-7 Report Type: Periodic Company Report Number: MS84533 Age: 31 YR Gender: Female Outcome PT Report Source Product Role Manufacturer Route Dose/Unit Duration Outcome PS Roche ORAL 1000000000000000000000000000000000000	Date: 10/23/1984				- <u>-</u>		NOCHE .	ORAL		140
Acturalgia Depression Noc Acturalgia Depression Noc Date: 10/18/1984 ISR Number: 303215-7 Report Type: Periodic Company Report Number: MS84533 Outcome PT Other Depression Noc Date: 10/18/1984 ISR Number: 303215-7 Report Type: Periodic Company Report Number: MS84533 Age: 31 YR Gender: Pemale Dose/Unit Duration Dose/Unit Duration Dose/Unit Duration Dose/Unit Duration Dottome PT Other Depression Noc Libido Decreased Date: 10/29/1984 ISR Number: 303612-X Report Type: Periodic Company Report Number: MS84580 Age: 42 YR Gender: Pemale Company Report Number: MS84580 Age: 42 YR Gender: Pemale Outcome PT Report Source Product Role Manufacturer MS84580 Outcome PT Report Source Product Role Manufacturer Route Dose/Unit Duration Female Outcome PT Report Source Product Role Manufacturer Route Dose/Unit Duration Dose/Unit Duration Female Outcome PT Report Source Product Role Manufacturer Route Role Roche Roc			Report Type: Periodic		Company Report Numbe	r: MS8457	2	Age: 32 YR	Gene	ler Famela
Depression Noc Accutane PS Roche ORAL 126 Date: 10/18/1984 ISR Number: 303215-7 Report Type: Periodic Company Report Number: MS84533 Age: 31 YR Gender: Pemale Outcome PT Report Source Product Role Manufacturer Route Depression Noc Libido Decreased PS Roche ORAL 140 Date: 10/29/1984 ISR Number: 303612-X Report Type: Periodic Company Report Number: MS84580 Age: 42 YR Gender: Pemale Outcome PT Report Source Product Role Manufacturer Route Dose/Unit Duration Date: 10/29/1984 ISR Number: 303612-X Report Type: Periodic Company Report Number: MS84580 Age: 42 YR Gender: Pemale Outcome PT Report Source Product Role Manufacturer Route Dose/Unit Duration Outcome PT Report Source Product Role Manufacturer Route Dose/Unit Duration Annecmia Nos Dyspnoca Nos	Outcome		Report Source	Product		Dolo	Manufactures			
Date: 10/18/1984 ISR Number: 303215-7 Report Type: Periodic Company Report Number: MS84533 Age: 31 YR Gender: Pemale Outcome PT Report Source Product Role Manufacturer Route Dose/Unit Duration Libido Decreased PS Roche ORAL 140 Date: 10/29/1984 ISR Number: 303612-X Report Type: Periodic Company Report Number: MS84580 Age: 42 YR Gender: Pemale Outcome PT Report Source Product Role Manufacturer Route Dose/Unit Duration Annemin Nos Dyspnoca Nos Accutance PS Roche ORAL 53		-		Accutane					Dose/Unit	
Outcome PT Report Type: Periodic Company Report Number: MS84533	Date: 10/18/1984							OKAL,		126
Other Depression Nec Libido Decreased Product Role Manufacturer Route Dose/Unit Duration Date: 10/29/1984 ISR Number: 303612-X Report Type: Periodic Company Report Number: MS84580 Age: 42 YR Gender: Pemale Outcome Product Role Manufacturer Route Dose/Unit Duration Annemin Nos Dyspnoce Nos Accutance PS Roche ORAL 53			Report Type: Periodic		Company Report Numbe	r: MS8453		Age: 31 YR	Gend	ler: Female
Libido Decreased Accutane PS Roche ORAL 140 Date: 10/29/1984 ISR Number: 303612-X Report Type: Periodic Company Report Number: MS84580 Age: 42 YR Gender: Pemale Outcome PT Report Source Product Role Manufacturer Route Dose/Unit Duration Ansemia Nos Dyspnoca Nos Accutane PS Roche ORAL 63			Report Source	Product		Role	Manufactures	-		
Dute: 10/29/1984 ISR Number: 303612-X Report Type: Periodic Company Report Number: MS84580 Age: 42 YR Gender: Female Outcome PT Report Source Product Role Manufacturer Route Dose/Unit Duration Annemin Nos Dyspnoca Nos Accutane PS Roche ORAL 63	Omer			Accutane	_				Dose/Unit	
Outcome PT Report Source Product Role Manufacturer Route Dose/Unit Duration Dyspnoca Nos Accutance PS Roche ORAL 63	Date: 10/29/1984		Denot The Date of					ORAL		140
Annemia Nos Dyspnoca Nos Report Source Product Role Manufacturer Route Dose/Unit Duration PS Roche ORAL 63	Outcome				Company Report Number	r: MS84580	1	Age: 42 YR	Gend	er: Female
Dyspacea Nos Accutane PS Roche ORAL 63	Ouscome		Report Source	Product		Roie	Manufacturer	Donta		
				Accutane					POSECULIK	
								ORAL		63

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		1	r college	Othiomalia g		diament .			
Date: 11/01/1984	ISR Number: 303920-2								
		Report Type: Periodic		Company Report Number: 8	4580		Age: 42 YR	Ger	nder: Female
Outcome	_ <u>PT</u>	Report Source	Product	R	ole	Manufacturer	Route	D#1 14	*
	Anaemia Nos Dyspnoea Nos		Accutane			Roche		Dose/Unit	Duration
	Palpitations			•	_	KOLIK	ORAL		63
Date: 11/13/1984	ISR Number: 305553-0								
,	tote (validae), 505555-0	Report Type: Periodic		Company Report Number: M	/IS8460	07	Age: 30 YR	Ge	nder: Female
Outcome	PT	Report Source	Product	_			•	- Gu	idei. Feinale
Hospitalization	Ear Disorder Nos		Accutane		ole_	Manufacturer	Route	Dose/Unit	Duration
Initial or Prolonged	Headache Nos		Accutable	PS.	3	Roche	ORAL		
	Psychotic Disorder Nos								
Date: 08/14/1984	ISR Number: 309598-6	Report Type: Expedited ((15-Day)	Company Report Number: M	10012	F4			
Outcome	PT				1.104.53	74	Age: 70 YR	Ger	ider: Male
Hospitalization -	Confusion	Report Source	Product	Re	ole	Manufacturer	Route	Dose/Unit	Duration
Initial or Prolonged	Eczema Nos		Accutane	PS	. —	Roche	ORAL		
Date: 08/24/1984	ISR Number: 309599-8						- CATL		60
	TOWN TAMBLES SON SANA-8	Report Type: Expedited (15-Day)	Company Report Number: M	f\$8438	38	Age: 24 YR	0	ıder: Male
Ontcome	PT	Report Source	Product		_		•	- Ga	. Maie
	Balanitis Nos		Accutane		e e	Manufacturer	Route	Dose/Unit	Duration
	Dry Skin		Accutane	PS		Roche	ORAL,		150
	Impotence								
	Pain Nos								
Date: 08/14/1984	ISR Number: 309606-2	Report Type: Periodic		Company Report Number: M			 		
Outcome	PT			Company Report Number: M	158435	1	Age: 20 YR	Gen	der: Male
	Depression Nec	Report Source	Product	Ro	le	Manufacturer	Route	Dose/Unit	Duration
			Accutane	PS		Roche	ORAL.	Dust Cilit	
Date: 09/03/1984	ISR Number: 309607-4	Report Type: Expedited (150
04		echort Type: Expedited (15-Day)	Company Report Number: M	S8442	5	Age: 39 YR	Gen	der: Female
Outcome	PT	Report Source	Product	Ro		Manufacturer	. .		
	Libido Decreased		Accutane	PS			Route	Dose/Unit	Duration
Date: 09/03/1984				ro		Roche	ORAL		95
Pate: 09/03/1984	ISR Number: 309610-4	Report Type: Expedited (15-Day)	Company Report Number: M	58426		A = 0 45 315		
Outcome	PT	Report Source	D 1	- • [moett 1/2			Age: 45 YR	Gen	der: Female
	Depression Nec	report source	Product		le	Manufacturer	Route	Dose/Unit	Duration
	Rash Maculo-Papular		Accutane	PS		Roche	ORAL		120
	Seborrhoea								120

			101007	District Reporting Of Information (F							
Date: 08/24/1984	ISR Number: 309617-7	Report Type: Expedited	(15-Day)	Company Report Number: M	58425	R1	Age: 18 \		_		
Outcome	_ PT	Report Source		1 - V F V -		54	Age: 18)	К	Gen	der: Male	
Other	Amnesia Nec	Report Source	Product		le_	Manufacturer	Route	Dose/t	J <u>nit</u>	Duration	
			Accutane	PS		Roche	ORAL			2	
Date: 09/06/1984	ISR Number: 311077-7	Report Type: Expedited	(15-Day)	Company Report Number: 84	102004	491001	Age: 5 Y	· · · · · · · · · · · · · · · · · · ·			_
Outcome	PT	Report Source	D	•			Age. 311	•	Gen	der: Maje	
Disability	Congenital Abnormality Nos	Health Professional	Product	Ro	_	Manufacturer	Route	Dose/U	Jnit	Duration	
	Hydrocephalus Nos	rada rio carong	Accutane	PS		Roche	ORAL			58	
	Нуротопіа		Tylenol	С			ORAL				
<u> </u>	Mental Retardation Severity Unspecified										
Date: 11/06/1984	ISR Number: 311571-9	Report Type: Periodic		Company Report Number: M	C04 F						_
Outcome	PT			ban't rehatetamingt. W:	J04~)	33.	Age: 38 Y	R	Gen	der: Female	
	Dysphonia	Report Source	Product	Rei	le	Manufacturer	Route	Dose/I	Jnit	Duration	
			Accutane	PS		Roche	ORAL			90	
Date: 12/18/1984	ISR Number: 311915-8	Report Type: Periodic		Company Report Number: MS	S8468	to	Age: 30 Y				_
Outcome	PT	Report Source	Product				Age. 301	K	Gen	der: Male	
	Impotence			Rol		Manufacturer	Route	Dose/U	Juit_	Duration	
	Libido Decreased		Accutane	PS		Roche	ORAL			27	
Date: 12/18/1984	ISR Number: 311921-3	Report Type: Periodic		Company Report Number: MS	\$8467	10					_
Outcome	_ PT	Report Source	n	1 p-t	uic 40)	0	Age: 44 Y	K	Gene	der: Female	
	Anxiety Nec	Acpoit Bouree	Product		le_	Manufacturer	Route	Dose/L	<u>init</u>	Duration	
	Ataxia Nec		Accutane	PS		Roche	ORAL				
	Multiple Sclerosis		Lithium	c			ORAL	G			
	Sedation		Ativan	c			ORAL				
			Seconal	c			ORAL				
			Unspecified	C			ORAL.				
Date: 12/18/1984	ISR Number: 311948-1	Report Type: Expedited (15-Day)	Company Report Number: MS	58467	6	Age: 35 N	ION	Gene	der: Male	_
Outcome	PT	Report Source	Product				=		Gall	wa. Male	
Hospitalization	Confusion		Accutane	Role	e_	Manufacturer	Route	Dose/L	Init	Duration	
Initial or Prolonged Other	Dermatitis Exfoliative Nos		Accurate	PS		Roche	ORAL			111	
Chic	Epistaxis Hyperlipidaemia Nos										

Date: 12/18/1984	ISR Number: 311950-X	Report Type: Expedited (1	(5-Day)	Company Report Numbe	r: MS84686	<u> </u>	Ages	32 YR	Gen	der: Male
Outcome	PT	Report Source	Product		Role	Manufacturer				
Death	Hypersensitivity Nos		Accutane		PS	Roche		oute	Dose/Unit	Duration
	Major Depressive Disorder Nos		Tofranil		C	Roche		RAL		119
Date: 11/23/1984	ISR Number: 312222-X	Report Type: Periodic		C				RAL		
Outcome	PT			Company Report Numbe	r: MS84607		Age:	30 YR	Gen	der: Female
Hospitalization -	Ear Disorder Nos	Report Source	Product		Role	Manufacturer	R	oute	Dose/Unit	Duration
Initial or Prolonged	Headache Nos		Accutane	_	PS	Roche		RAL		126
	Psychotic Disorder Nos									120
Date: 11/08/1984]	ISR Number: 312873-2	Report Type: Periodic		Community of	1.504.4					
Outcome	PT			Company Report Numbe	r: MS84425		Age:	39 YR	Gen	der: Female
	Libido Decreased	Report Source	Product		Role	Manufacturer	Re	oute	Dose/Unit	Duration
			Accutane		PS	Roche		RAL,		90
	SR Number: 313432-8	Report Type: Periodic		Company Report Number	: MS84710		Age:	70 YR		der: Unknown
Outcome	PT	Report Source	Product				-		Gq	Mei. Unknown
Other	Amnesia Nec		Accutane		Role	Manufacturer		oute	Dose/Unit	Duration
Date: 01/10/1985 I	SR Number: 313445-6				PS	Roche	OF	RAL		
•		Report Type: Periodic		Company Report Number	: MS84709		Age:	19 YR	Gen	der: Male
Outcome	PT	Report Source	Product		Role					
	Abnormal Dreams		Accutane		PS	Manufacturer		oute	Dose/Unit	Duration
	Depression Nec		Septra Ds			Roche		RAL		138
	Sweating Increased		Ampicillin		C		OF	RAL.		
			Keflex		c		OF	RAL	G	
			Cleocin Het		c		OF	RAL	G	9
Date: 12/28/1984 I	SR Number: 313485-7	D			С		OF	RAL		
Outcome		Report Type: Expedited (15	-Day)	Company Report Number	: MS84696		Age:	23 YR	Gen	der: Male
	PT	Report Source	Product		Role	Manufacturer	D.	ute	Dog / Int	D #
Hospitalization - Initial or Prolonged	Depression Nec Paranoia		Accutane		PS	Roche			Dose/Unit	Duration
	I WIENOIS		Tofranil		C	route.		AL.		120
	SR Number: 313517-6	Report Type: Expedited (15	-Day)	Company Report Number			Age:	AL	Genzi	der: Male
Outcome	<u>PT</u>	Report Source	Product		Dala	Manut	-			•
	Personality Disorder Nos		Accutane		Role	Manufacturer		ute	Dose/Unit	Duration
				_	PS	Roche	OR	AL		

	100		Sylone	Event Reporting S Minternation (E)	is year and a second	EN .		
Date: 12/28/1984	ISR Number: 313607-8							
		Report Type: Expedited	(15-Day)	Company Report Number: MS	34708	Age: 52 YR	Gen	ider: Female
Outcome	_ <u>PT</u>	Report Source	Product	Role	Manufacturer	Route	D	
Hospitalization - Initial or Prolonged	Confusion Convulsions Nos	Health Professional	Accetane	PS	Roche	ORAL	Dose/Unit	Duration
Other	Headache Nos		Hytone	c	Rocard	ORAL		35
	Pyrexia		Decadron	c				
Date: 12/28/1984	ISR Number: 313608-X	Report Type: Expedited	(15-Day)	Company Report Number: MSS	24704			 -
Outcome	PŢ	Report Source			14700	Age: 43 YR	Gen	der: Female
Other	Depression Nec	Health Professional	Product	Role		Route	Dose/Unit	Duration
	Dermatitis Nos	. restor i torceatoral	Accutane	PS	Roche	ORAL		
	Emotional Disturbance Nos		Keflex	С				
D	Nervousness	<u>.</u>	Mycostatin	C		,		
Date: 12/28/1984	ISR Number: 313610-8	Report Type: Expedited	(15-Day)	Company Report Number: MS8	4714	Age: 13 YR		
Outcome	PT	Report Source	Product			•	Gen	der: Unknown
	Depression Nec		Accutane	Role	Manufacturer		Dose/Unit	Duration
D-4 1200/10":				PS	Roche	ORAL		
Date: 12/28/1984	ISR Number: 313636-4	Report Type: Expedited	(15-Day)	Company Report Number: MS8	4709	Age: 19 YR	· · · ·	J., 1/1
Outcome	PT	Report Source	Product				Gen	der: Male
	Abnormal Dreams		Accutane	Role	Manufacturer	Route	Dose/Unit	Duration
	Depression Nec		Erythromycir	PS	Roche	ORAL		138
	Sweating Increased		Ampicillin	9		ORAL	G	
			Septra Ds	c		ORAL	G	
			Keflex	c		ORAL		10
Date: 12/28/1984	ISR Number: 313641-8	D		C		ORAL		1
		Report Type: Expedited	(15-Day)	Company Report Number: MS8	4710	Age: 70 YR	Gen	der: Unknown
Outcome	_ <u>PT</u>	Report Source	Product	Role	Manufacturer	David-		
Other	Amnesia Nec		Accutane	PS	Roche	Route	Dose/Unit	Duration
Date: 12/28/1984	ISR Number: 313643-1					ORAL		
	1-040-1-1 (1-040-1	Report Type: Expedited	(15-Day)	Company Report Number: MS8	4711	Age:	Gen	der: Unknown
Outcome	PT	Report Source	Product	Role	Manufacturer	n		Cincioni
Other	Amnesia Nec			Kole Kole	Manulacturer	Route	Dose/Unit	Duration

Date: 01/04/1985	ISR Number: 313711-4	Report Type: Periodic		Company Report Numbe	r: MS8426	0	Age: 29 YR	Car	der: Male
Outcome	PT	Report Source	Product		Role	M-6-4-			
Other	Dysphonia Neoplasm Nos		Accutane		PS	Manufacturer Roche	Route ORAL	Dose/Unit	Duration 120
Date: 12/19/1984	ISR Number: 314914-5	Report Type: Periodic		Company Report Numbe	r: MS8466	1	Age: 17 YR	Ger	der: Male
Outcome	PT	Report Source	Product		Role	M	_		
Other	Depression Nec		Accutane	· · · · · · · · · · · · · · · · · · ·	PS	Manufacturer Roche	Route ORAL	Dose/Unit	Duration 47
Date: 12/19/1984	ISR Number: 314930-3	Report Type: Expedited (15-Day)	Company Report Numbe	r: MS8466	4	Age: 21 YR	Ger	der: Male
Outcome Hospitalization -	Convulsions Nos	Report Source	Product	_	Role	Manufacturer	Route	Dose/Unit	
Initial or Prolonged	Schizophrenia Nos		Accutane		PS	Roche	ORAL	Deservatt	Duration
		····	Tetracycline		C		ORAL		88
Date: 01/04/1985 Outcome	ISR Number: 315186-8	Report Type: Periodic		Company Report Numbe	r: MS8471	4	Age: 13 YR	Gen	der: Unknown
Outcome	PT Depression Nec	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
			Accutane		PS		ORAL	Does Ont	Duration
Outcome	ISR Number: 315189-3 PT	Report Type: Periodic		Company Report Number	r: MS8470	8	Age: 52 YR	Gen	der: Female
<u> </u>	Confusion	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
			Accutane		PS	Roche	ORAL	<u> </u>	Ditation
Date: 01/17/1985	ISR Number: 315194-7	Report Type: Periodic		Company Report Number	: MS856		Age: 18 YR	Gen	der: Male
Outcome	PT Annesia Nec	Report Source	Product		Role	Manufacturer	Route		
	Autoresia Nec		Accutane		PS PS	Roche	ORAL	Dose/Unit	Duration
Date: 12/21/1984	ISR Number: 315346-6	Report Type: Periodic		Company Report Number	: MS84676	5	Age: 35 YR	Gen	der: Male
Outcome	PT	Report Source	Product		Role	Manufacturer			
Hospitalization Initial or Prolonged	Confusion Dermatitis Exfoliative Nos		Accutane		PS	Roche	ORAL	Dose/Unit	Duration 111
	Epistaxis Hyperlipidaemia Nos								
Date: 12/21/1984	ISR Number: 315352-1	Report Type: Periodic		Company Report Number	: MS84680	· · · · · · · · · · · · · · · · · · ·	Age: 30 YR		der: Male
Outcome	PT	Report Source	Product		Dala	Manager	_		
	Impotence Libido Decressed		Accutane		Role PS	Manufacturer Roche	Route ORAL	Dose/Unit	Duration 27
08/03/2000									21

				e Dyent Recording					
				Of talorandon gr		(CHEE)	100		
Date: 12/21/1984	ISR Number: 315364-8	Report Type: Periodic		Company Report Number: M	00460				
Outcome	PT	72 40		Company Report Aumber: M	58468	6	Age: 32 YR	Gen	der: Male
Death	Death	Report Source	Product	Ro	le	Manufacturer	Route	Dose/Unit	Duration
	Depression Nec		Accutane	PS		Roche	ORAL		119
	Non-Accidental Overdose		Tofranil	С			ORAL		*1.7
Date: 01/17/1985	ISR Number: 316137-2	Report Type: Periodic		Company Report Number: M	S855		Age: 36 YR	- Cen	der: Female
Outcome	<u>PT</u>	Report Source	Product	ъ.			•	-	Tunale,
Other	Thinking Abnormal Nec		Accutane	Ro	le_	Manufacturer	Route	Dose/Unit	Duration
Date: 01/04/1985				PS		Roche	ORAL		
Date: 01/04/1982	ISR Number: 316307-3	Report Type: Periodic		Company Report Number: M.	S84695	5	Age:		der: Male
Outcome	PT	Report Source	Product				age.	Gen	der: Male
	Personality Disorder Nos		Accutane	<u>Ro</u>	<u>e</u> _	Manufacturer	Route	Dose/Unit	Duration
D.4. 01044555		 	Accutable	PS		Roche	ORAL		
Date: 01/04/1985	ISR Number: 316308-5	Report Type: Periodic		Company Report Number: Mi	584696	5	Age: 23 YR		
Outcome	PT	Report Source	Product				nge. 23 IK	Gen	der: Male
Hospitalization -	Agitation		Accutane		<u>e</u>	Manufacturer	Route	Dose/Unit	Duration
Initial or Prolonged	Depression Nec		Tofranil	PS		Roche	ORAL		120
	Paranoia		TOITAILI	c			ORAL		
Date: 09/12/1984	ISR Number: 316444-3	Report Type: Expedited	(15-Day)	Company Report Number: MS			1 A0.717		
Outcome	_ PT	Report Source	Product	r v r r r r r r r r r r r r r r r r r r	,,,,,,,	-	Age: 30 YR	Gen	der: Female
Other	Depression Nec			Rol	<u>e</u> _	Manufacturer	Route	Dese/Unit	Duration
			Accutane	PS		Roche	ORAL		60
Date: 09/11/1984	ISR Number: 316445-5	Report Type: Expedited	15-Day)	Company Report Number: MS	84425			-	
Outcome	_ PT	Report Source	-		·v 11 43		Age: 39 YR	Gen	der: Female
Death	Libido Decreased	Acport source	Product		b	Manufacturer	Route	Dose/Unit	Duration
			Accutane	PS		Roche	ORAL		
Date: 09/12/1984	ISR Number: 316454-6	Report Type: Expedited (15-Day)	Company Report Number: MS	94433				
Outcome	_ PT	Report Source			104433		Age: 35 YR	Gene	der: Female
Other	Depression Nec		Product	Role	<u>.</u>	Manufacturer	Route	Dose/Unit	Duration
			Accutane	PS		Roche	ORAL		73
Date: 09/12/1984	ISR Number: 316527-8	Report Type: Expedited (15-Day)	Company Report Number: MS	01121		-		
Outcome	_ PT	Report Source	• • • • • • • • • • • • • • • • • • • •		04430		Age:	Gend	ler: Female
	Cleft Palate	seport source	Product	Role	<u>.</u>	Manufacturer	Route	Dose/Unit	Duration
	Deafness Nos		Accutane	PS		Roche	ORAL		180

Date: 01/04/1985	ISR Number: 316580-1	Report Type: Periodic		Company Report Numb	er: MS8471		Age;		
Outcome	PT	Report Source	Product	- , ,			•	Gen	der: Unknown
Other	Amnesia Nec		Accutance		Role PS	Manufacturer Roche	Route	Dese/Unit	Duration
Date: 01/14/1985	ISR Number: 317661-9	Report Type: Periodic		Company Report Number	Mc954	 	···········	· <u> </u>	
Outcome	P T	Report Source	D		1. M3050		Age:	Gen	der: Unknown
Other	Amnesia Nec		Product		Role	Manufacturer	Route	Dose/Unit	Duration
	·		Accutane		PS	Roche	ORAL		
Date: 01/14/1985	ISR Number: 317662-0	Report Type: Periodic		Company Report Numbe	r: MS855		Age:	Conv	ler: Unknown
Outcome	<u>PT</u>	Report Source	Product		n.s.	35	-		er. Unknown
Other	Amnesia Nec		Accutane		Role PS	Manufacturer	Route	Dose/Unit	Duration
Date: 01/29/1985	ICD No. 1 210552				1.9	Roche	ORAL		
	ISR Number: 319553-8	Report Type: Expedited (15-Day)	Company Report Numbe	r: 0004400)1	Age: 25 YR	Geno	lare Male
Outcome	PT	Report Source	Product					GENO	ler: Male
Hospitalization - Initial or Prolonged	Psychotic Disorder Nos		Accutane		Role PS	Manufacturer	Route	Dose/Unit	Duration
- Totalged			Lithium		C	Roche	ORAL		
Date: 02/04/1985	ISR Number: 319614-3	Report Type: Periodic	~	C				-	730
Outcome	PT			Company Report Numbe	r: 8502000	6	Age: 26 YR	Gene	ler: Male
	Back Pain	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration .
	Cyst Nos		Accutane		PS	Roche	ORAL		214
	Depression Nec								214
Date: 02/04/1985	ISR Number: 319620-9	Report Type: Periodic		Company Report Number	- 8502000	4			
Outcome	_ PT	Report Source	Product	, , P	. 0502000	•	Age: 25 YR	Gend	ler: Male
Hospitalization -	Psychotic Disorder Nos		Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
Initial or Prolonged			Acculane Lithium		PS	Roche	ORAL		232
Date: 09/21/1984	ISR Number: 322240-3	P 45	- Minori		С				730
		Report Type: Periodic		Company Report Number	: MS84472	2	Age: 20 YR	Gend	er: Female
Outcome	<u>PT</u>	Report Source	Product		Role	Manufacturer	-		
Other	Depression Nec	_	Accutane		PS	Roche	Route	Dose/Unit	Duration
			Atarax		c	awadit	ORAL		32
Date: 02/05/1985	ISR Number: 322402-5	Report Type: Expedited (1	5-Day)	Company Report Number		<u></u>	ORAL Age: 26 YR		
Outcome	<u>PT</u>	Report Source	Product				Age: 20 YK	Gend	er: Male
Other	Headache Nos		Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
			Accutane		PS	Roche	ORAL	· -	

i i	Report Type: Periodic		Company Report Numbe	r: 8502001	1	Age: 24 YR	C-	der: Female
<u>PT</u>	Report Source	Product						
Dysphonia		Accutane	·				Dose/Unit	Duration
ICD N 226420 6	-					URAL		600
	Report Type: Periodic		Company Report Number	er: 8502000	6	Age: 26 YR	Gen	der: Male
	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
Pain Nos		Accutane		PS	Roche	ORAL		<u></u>
Thinking Abnormal Nec								
ISR Number: 330947-7	Report Type: Periodic		Company Report Number	r: 8502000	9	Ann 26 VD		1
PT	Report Source	Product				nge. 201K	Gen	der: Male
Readache Nos						Route	Dose/Unit	Duration
••					Roche	ORAL		
			ıs					
		Captopril		-				
ISR Number: 337875-1	Report Type: Periodic		Company Report Numbe		7	· · · · · · · · · · · · · · · · · · ·		der: Male
PT	Report Source	Product				_		uct. Male
Hypotension							Dose/Unit	Duration
Personality Disorder Nos					Roche	ORAL.		125
		Midrin		-				
ISR Number: 339601-9	Report Type: Expedited (5-Day)	Company Report Numbe	r: 8502002		Age: 16 YR	Gen	der: Male
<u>PT</u>	Report Source	Product		Role	Manufactures	Dt.		
Depression Nec	_	Accutane					Dose/Unit	Duration
ISR Number: 339610-X	Denved Town Day Pr. 10					OKAL		141
		13-Day)	Company Report Numbe	r: 8502003	7	Age: 16 YR	Gen	der: Male
	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
Personality Disorder Nos		Accutane		PS	Roche	ORAL		141
Postural Hypotension				С				
		Midrin	<u>-</u>	С	<u>.</u>			
	Report Type: Periodic		Company Report Number	r: 0028100		Age: 16 YR	Gen	der: Male
	Report Source	Product		Role	Manufacturer	Route	Dose/Linit	Duration
Depression Nec		Accutane		PS	Roche	ORAL		141
	Dysphonia ISR Number: 326430-5 PT Depression Nee Pain Nos Thinking Abnormal Nec ISR Number: 330947-7 PT Headache Nos Hypertension Nos Insomnia Nec Nausea ISR Number: 337875-1 PT Hypotension Personality Disorder Nos ISR Number: 339601-9 PT Depression Nec ISR Number: 339610-X PT Arthritis Nos Personality Disorder Nos	Dysphonia ISR Number: 326430-5 PT Depression Nee Pain Nos Thinking Abnormal Nec ISR Number: 330947-7 Report Type: Periodic PT Report Source Pain Nos Hypertension Nos Insormin Nec Nausea ISR Number: 337875-1 Report Type: Periodic PT Report Type: Periodic Report Type: Periodic PT Report Type: Periodic Report Type: Periodic Report Type: Periodic Report Source ISR Number: 339601-9 PT Depression Nec ISR Number: 339610-X Report Type: Expedited (1) PT Arthritis Nos Personality Disorder Nos	Dysphonia Accutane ISR Number: 326430-5 Report Type: Periodic PT Report Source Product Depression Nec Pain Nos Thinking Abnormal Nec ISR Number: 330947-7 Report Source Product PT Report Source Product Accutane IsR Number: 330947-7 Report Type: Periodic PT Report Source Product Accutane Inderal Multivitamir Captopril ISR Number: 337875-1 Report Type: Periodic PT Report Type: Periodic PT Report Source Product Accutane Hypotension Personality Disorder Nos Personality Disorder Nos PT Report Source Product Accutane Fiorinal Midrin ISR Number: 339601-9 Report Type: Expedited (15-Day) PT Report Source Product Accutane ISR Number: 339610-X Report Type: Expedited (15-Day) PT Report Source Product Accutane ISR Number: 339610-X Report Source Product Arthritis Nos Personality Disorder Nos Postural Hypotension Fiorinal Midrin ISR Number: 342031-7 Report Type: Periodic PT Report Source Product Accutane Fiorinal Midrin ISR Number: 342031-7 Report Type: Periodic PT Report Source Product PT Report Type: Periodic	Dysphonia Report Type: Periodic Depression Nec Pain Nos PT Report Source Product Depression Nec Pain Nos Report Type: Periodic ISR Number: 330947-7 Report Type: Periodic Report Source Product Accutanc ISR Number: 330947-7 Report Source Product Report Source Product Accutanc Inderal Multivitamins Captopril ISR Number: 337875-1 Report Type: Periodic Company Report Number PT Report Source Product Accutanc ISR Number: 337875-1 Report Type: Periodic Company Report Number PT Report Source Product Accutanc Product Accutanc Product Accutanc ISR Number: 339601-9 Report Type: Expedited (15-Day) Company Report Number PT Report Source Product Accutanc ISR Number: 339610-X Report Type: Expedited (15-Day) Company Report Number PT Arthritis Nos Personality Disorder Nos Personality Disor	Dysphonia Report Source Product Role PT Report Source Product Role Pain Nos Thinking Abnormal Nec ISR Number: 330947-7 Report Type: Periodic Report Source Product Role PT Report Source Product Role PT Report Source Product Role ISR Number: 330947-7 Report Type: Periodic Role PT Report Source Product Role Indernal C Company Report Number: 8502000 Role PT Report Source Product Role Indernal C Captopril C Company Report Number: 8502000 ISR Number: 337875-1 Report Type: Periodic Company Report Number: 8502003 PT Report Source Product Role Hypotension Personality Disorder Nos Personality Disorder Nos PER Report Source Product Role ISR Number: 339601-9 Report Type: Expedited (15-Day) Company Report Number: 8502003 PT Report Source Product Role ISR Number: 339610-X Report Type: Expedited (15-Day) Company Report Number: 8502003 PT Report Source Product Role Accutance PS ISR Number: 339610-X Report Type: Expedited (15-Day) Company Report Number: 8502003 PT Report Source Product Role Accutance PS ISR Number: 339610-X Report Type: Expedited (15-Day) Company Report Number: 8502003 PT Report Source Product Role Accutance PS ISR Number: 342031-7 Report Type: Periodic Company Report Number: 8502003 ISR Number: 342031-7 Report Type: Periodic Company Report Number: 00281001 ISR Number: 342031-7 Report Type: Periodic Company Report Number: 00281001	Dysphonia Report Type: Periodic Company Report Number: 85020016 PT Report Source Product Role Manufacturer	Dysphonia	PT

		197 4)		Event Reporting		ferri (A.E.(ES))			
			2000	Markeyn attend		Report, 201			
Date: 03/12/1985	ISR Number: 342555-2	Report Type: Expedited ((15-Day)	Company Report Number:	850200	24	Age: 21 YR	Ger	ider; Male
Outcome	PT	Report Source	Product	T	tole	Manufacturer			
Other	Confusion		Accutane		S		Route	Dose/Unit	Duration
	Hair Disorder Nos Sedation		Erythromycir	-		Roche	ORAL		153
	Weight Decreased		Motrin				ORAL		
Date: 05/07/1985					; 		ORAL	G	
Date: 03/0//1983	ISR Number: 342863-5	Report Type: Expedited (15-Day)	Company Report Number: (0053200	01	Age: 16 YR	Ger	ider: Male
Outcome	PT	Report Source	Product				•		ruei. Maje
Other	Depression Nec		Accutane		ole	Manufacturer	Route	Dose/Unit	Duration
	Personality Disorder Nos		Accidant	P	S	Roche	ORAL		158
Date: 03/15/1985	ISR Number: 343680-2	Report Type: Periodic		Company Report Number: (V) 105~				
Outcome	PT	_		comban't rehatt tampet: (v1920I	11	Age: 17 YR	Ger	der: Male
	Impotence	Report Source	Product	R	ole	Manufacturer	Route	Dose/Unit	Duration
<u>-</u>		_	Accutane	P	S	Roche	ORAL		121
Date: 03/15/1985	ISR Number: 343683-8	Report Type: Periodic		C					
Outcome	PT			Company Report Number: 0	1025400)1	Age: 25 YR	Ger	ider: Male
	Amnesia Nec	Report Source	Product	R	ole	Manufacturer	Route	Dose/Unit	Duration
	Headache Nos		Accutane	P:	3	Roche	ORAL	Dust offic	Datation
	Vision Abnormal Nec						on E		
Date: 05/09/1985	ISR Number: 344137-5	Report Type: Periodic						<u>-</u>	
Outcome		Report type: Periodic		Company Report Number: 0	038600	11	Age: 13 YR	Gen	der: Female
	PT P	Report Source	Product	R	ole	Manufacturer	Dowle	D #1-14	ALC: U.S.
Hospitalization - Initial or Prolonged	Depression Nec Hyperlipidaemia Nos		Accutane		_	Roche	Route	Dose/Unit	Duration
	Menometrorhagia		Tetracycline	c		and the	ORAL		140
Date: 05/10/1985		 -							
Date. 05/10/1985	ISR Number: 344273-3	Report Type: Periodic		Company Report Number: N	1 S8429	4	Age: 16 YR		der: Male
Outcome	PT	Report Source	Product				ge. 10 IR	Gen	der: Male
Other	Impotence		Accutane		ole_	Manufacturer	Route	Dose/Unit	Duration
			Accutance	PS	6	Roche	ORAL		67
Date: 05/09/1985	ISR Number: 344498-7	Report Type: Periodic	-	Company Report Number: 0	023000				
Outcome	PT	Dominat C.			V23UUU		Age: 20 YR	Gen	der: Male
Hospitalization -	Psychotic Disorder Nos	Report Source	Product	<u>R</u>	ole_	Manufacturer	Route	Dose/Unit	Duration
initial or Prolonged			Accutane	PS	;	Roche	ORAL		
Other									

		' F	e e e e e e e e e e e e e e e e e e e	Event Reporti Di information		Barrer III				
D.4 DENOUGES										
Date: 05/10/1985	ISR Number: 345135-8	Report Type: Periodic		Company Report Number	r: MS8440	12	Age:	17 YR	Gen	ıder: Male
Outcome	PT PI LIP W	Report Source	Product	_	Role	Manufacturer	D,	oute	D	5
Hospitalization - Initial or Prolonged	Blood Alkaline Phosphatase Nos Increased Schizophrenia Nos		Accutane		PS	Roche		RAL	Dose/Unit_	Duration 142
Date: 05/10/1985	ISR Number: 345136-X	Report Type: Periodic		Company Report Numbe	r: 0028500)1	Age:	39 YR		ider: Female
Outcome	PT	Report Source	Product						Gai	toer: remate
	Arthralgia		Accutane		Role	Manufacturer	<u>R</u> c	ute	Dose/Unit	Duration
	Myadgia		Thyroid		PS	Roche	OF	RAL		72
	Tenosynovitis Thinking Abnormal Nec		* II y TOIG		С		OF	tAL .	MG	
Date: 05/10/1985	ISR Number: 345192-9	Report Type: Periodic		Company Report Numbe	r: 0001000	1	Age:	33 YR	Gen	der: Female
Outcome	PT	Report Source	Product		Role	Manufacturer	n.		D. are	
	Arthralgia Back Pain		Accutane		PS	Roche		ute	Dose/Unit	Duration
	Insomnia Nec				10	Kodie	OF	LAL		112
Date: 04/17/1985	ISR Number: 345326-6	Report Type: Expedited (1	5-Day)	Company Report Numbe	r: 8502004	2	Age:	43 YR	Gen	der: Male
Outcome	_ <u>PT</u>	Report Source	Product		Role	Manufacturer	n.			
·	Depression Nec Emotional Disturbance Nos		Accutane		PS	Roche		ate AL	Dose/Unit	Duration
Date: 05/10/1985	ISR Number: 345385-0	Report Type: Periodic		Company Report Number	MS8429	5	Age:	50 YR	Gen	der: Female
Outcome	PT	Report Source	Product		Role	Mount				
Other	Anxiety Nec		Accutane		PS	Manufacturer		ute	Dose/Unit	Duration
	_		Sumyein Hel		rs C	Roche	OR			
Date: 05/10/1985	ISR Number: 345405-3	Report Type: Periodic		Company Report Number			OR			
Outcome	PT	Report Source	ъ ч	* surpore tuninei	. 5010500	•	Age:	16 YR	Gen	der: Male
Other	Alopecia	verbort source	Product		Role	Manufacturer	Ro	ute	Dose/Unit	Duration
	Nail Disorder Nos Personality Disorder Nos		Accutane		PS	Roche	OR	AL		100
Date: 04/29/1985	ISR Number: 345740-9	Report Type: Expedited (1:	5-Day)	Company Report Number	: 00524001		Age:	46 YR		
Outcome	PT	Report Source	Product				, age:	40 1 K	Gene	der: Male
	Libido Decreased				Role	Manufacturer	Ro	ute	Dose/Unit	Duration
			Accutane		PS	Roche	OR	AT.		228

		55		e Breit Reports	2.7	(4.5)			Marie Contract
		444		Ul Internatia)		PODE CO			
Date: 05/10/1985	ISR Number: 345888-9	Report Type: Periodic		Company Report Numbe	r: 0039200	D1	Age: 17 YR		nder: Male
Outcome	PT	Report Source	Product				17 IK	. Ga	nder: Male
Other	Alopecia		Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
·····	Palpitations		Acculance		PS	Roche	ORAL		112
Date: 05/01/1985	ISR Number: 349045-1	Report Type: Periodic		Company Report Numbe	0052404				
Outcome	PT ·			contrary report runne	r: 0032400	71	Age: 46 YR	Ger	nder: Male
	Libido Decreased	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
			Accutane		PS	Roche	ORAL,		228
Date: 05/09/1985	ISR Number: 349792-1	Report Type: Periodic		Company Report Number	Megane				
Outcome	PT	Report Source		whent we have to mitter	. 1130430		Age: 18 YR	Ge	nder: Male
Other	Depression Nec	vebou source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Thinking Abnormal Nec		Accutane		PS	Roche	ORAL	· -	29
Date: 05/10/1985	ISR Number: 350264-9	Report Type: Periodic		Company B					
Outcome	PT			Company Report Number	r: 0020500	01	Age: 19 YR	Ges	ader: Female
	Acne Nos	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Depression Nec		Accutanc		PS	Roche	ORAL		120
	Drug Ineffective								120
Date: 05/10/1985	ISR Number: 350278-9	Report Type: Periodic		G					
Outcome	PT			Company Report Number	: 0001700	1	Age: 32 YR	Gen	ider: Female
Other	Palpitations	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
			Accutane		PS	Roche	ORAL.	-	44
Date: 05/10/1985	ISR Number: 350281-9	Report Type: Periodic			<u>97 </u>				71
Outcome	PT			Company Report Number	0001500	1	Age: 20 YR	Gen	ıder: Female
	Alopecia	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Anxiety Nec		Accutane		PS	Roche	ORAL		126
	Asthenia								120
	Dizziness (Exc Vertigo)								
Date: 05/10/1985	ISR Number: 350295-9	Report Type: Periodic		Company Day - + 3					
Outcome	PT			Company Report Number	: MS84214	1	Age: 20 YR	Gen	ider: Female
Other	Insomnia Nec	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	- ~		Accutane		PS	Roche	ORAL		

	-		reston	a Event Reports Of Integration		Report			
Date: 05/10/1985	ISR Number: 350330-8	Report Type: Periodic	-	Company Report Numb	er: 000780	01	Age: 30 YR	C=	der: Male
Outcome	PT	Report Source	Product		b. 1		•		waie
	Impotence		Accutane		Role PS	Manufacturer Roche	Route	Dose/Unit	Duration
Date: 05/10/1985	TOP N. A. DEGGG.				го	Roche	ORAL		69
	ISR Number: 350576-9	Report Type: Periodic		Company Report Number	er: MS8471	19	Age: 26 YR	Gen	der: Female
Outcome	PT	Report Source	Product		n)			
Other	Depression Nec		Accutane		Role PS	Manufacturer Roche	Route	Dose/Unit	Duration
	Myalgia Rectal Bleeding				ra	Roche	ORAL		43
Date: 06/27/1985	ISR Number: 354278-4	Report Type: Expedited	(15 Dev)						
Outcome	PT		(av-vay)	Company Report Number	er: 0072600	01	Age: 24 YR	Gen	der: Female
	Myalgia	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Palpitations		Accutane		PS	Roche	ORAL		47
	Tachycardia Nos		Modicon		С				**/
Date: 06/25/1985	ISR Number: 354283-8	Report Type: Expedited	(15-Day)	Company Report Numbe		n:			
Outcome	_ PT	Report Source			::: 0003200	91	Age: 17 YR	Gan	der: Male
Hospitalization -	Aphasia	Acchora gont ce	Product		Role	Manufacturer	Route	Dose/Unit	Duration
Initial or Prolonged	Carotid Artery Stenosis Hemiplegia		Accutane		PS	Roche	ORAL		
Date: 10/07/1985	ISR Number: 366392-8								
-		Report Type: Periodic		Company Report Numbe	r: 0114700	01	Age: 49 YR	Gen	der: Female
Outcome	_ <u>PT</u>	Report Source	Product		Role	Manufacturer	. Bud		
	Amnesia Nec Dry Skin		Accutane		PS	Roche	Route	Dose/Unit	Duration
	Dry Skin Myopathy				ra	Roche	ORAL		128
	Vision Abnormal Nec								
Date: 10/16/1985	ISR Number: 367370-5								
		Report Type: Periodic		Company Report Numbe	r. 0121700)ı	Age: 15 YR	Gen	der: Male
Outcome	<u>PT</u>	Report Source	Product		Role	Manufacturer	Donts		
Death	Depression Nec		Accutane		PS	Roche	Route ORAL	Dose/Unit_	Duration
Date: 10/17/1985	ISR Number: 368132-5	Report Type: Expedited (15-Day)	C D			UKAL		29
Outcome	PT		~uj)	Company Report Number	r: 0121700	11	Age: 15 YR	Gene	der: Male
Death	Depression Nec	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	•		Accutane		PS	Roche	ORAL.		29

		10 A	e e e e e e e e e e e e e e e e e e e	e Prent Repositi Of Information		em en co Region			
Date: 10/24/1985	ISR Number: 372390-0	Report Type: Periodic		Company Report Numbe	r: MS8442	6	Age: 45 YR	Gen	ıder: Female
Outcome	PT	Report Source	Product		Role	Manufacturer	-		
	Condition Aggravated		Accutane		PS	Roche	Route	Dose/Unit	Duration
	Depression Nec Seborrhoea	•			13	Roche	ORAL		120
	Skin Disorder Nos								
Date: 12/01/1985	ISR Number: 373016-2								
	15K (4minber: 3/3010-2	Report Type: Expedited (15-Day)	Company Report Number	r: 0154800	1	Age: 22 YR	Gen	ider: Female
Outcome	PT	Report Source	Product		D-1-	35			
Hospitalization - Initial or Prolonged	Cerebrovascular Disorder Nos	Foreign	Асситале		Role_ PS	Manufacturer	Route	Dose/Unit	Duration
minute or 1 toloniged	Hirsutism Hyporeflexia				гэ .	Roche	ORAL		17
	Psychotic Disorder Nos								
Date: 10/23/1985	ISR Number: 373113-1								
	15K Number: 3/3113-1	Report Type: Periodic		Company Report Number	: MS84426	5	Age: 45 YR	Gen	der: Female
Outcome	<u>PT</u>	Report Source	Product		D.1				1 cattage
	Condition Aggravated		Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
	Depression Nec Heat Rash		. ADVOIDING		PS	Roche	ORAL		
	Seborrhoea								
Date: 12/10/1985									
Date: 12510/1985	ISR Number: 376051-3	Report Type: Periodic		Company Report Number	: 0114700	l	Age: 49 YR	Cen	der: Female
Outcome	PT	Report Source	Product				•	Odi	uer: remaie
	Amnesia Nec		Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
	Dry Skin		recutant		PS	Roche	ORAL		90
	Myopathy Vision Abnormal Nec								
Date: 01/07/1986									
Date: 01/0//1986	ISR Number: 378385-5	Report Type: Periodic		Company Report Number	: 00747001		Age: 35 YR	Gene	day ver
Outcome	PT	Report Source	Product				-	Gene	der: Male
	Confusion	- 	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
	Epistaxis		verneratio		PS	Roche	ORAL		111
	Headache Nos Hyperlipidaemia Nos								
Date: 02/10/1986	· · · · · · · · · · · · · · · · · · ·								
Pare. 02/10/1980	ISR Number: 384028-7	Report Type: Periodic		Company Report Number	00112001		Age: 38 YR		d 7 .
Ontcome	PT	Report Source	Product				-	Gene	der: Female
Other	Palpitations		Accutanc		Role_	Manufacturer	Route	Dose/Unit	Duration
			Accutanc		PS	Roche	ORAL		111

			200000	e Event (kopus UK Informatio		Rojon			
Date: 02/11/1986	ISR Number: 384033-0	Report Type: Expedited	(15-Day)	Company Report Num	ber: 00188	001	Age: 43 YR	Ger	nder: Fenule
Outcome	<u>PT</u>	Report Source	Product						idei: remaje
Hospitalization -	Alopecia	Literature	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
Initial or Prolonged	Cheilitis Comeal Ulcer Nec Depression Nec		Acculance		PS	Roche	ORAL		244
Date: 02/25/1986	ISR Number: 384455-8	Report Type: Expedited	(15-Day)	Company Report Num	ber: 860200	057001	Age: 15 YR	Ger	nder: Female
Outcome	<u>PT</u>	Report Source	Product						1.cusie
Hospitalization - Initial or Prolonged	Arthralgia	Health Professional	Accutane	· · · · · · · · · · · · · · · · · · ·	PS PS	Manufacturer	Route	Dose/Unit	Duration
Tillian of Prototiged	Depression Nec Personality Disorder Nos Syncope				rs	Roche	ORAL		28
Date: 03/05/1986 Outcome	ISR Number: 385499-2	Report Type: Expedited	(15-Day)	Company Report Num	ber: 860101	669001	Age: 22 YR	Ger	nder: Male
Hospitalization -	PT Personality Disorder Nos	Report Source	Product	_	Role	Manufacturer	Route	Dose/Unit	D41
Initial or Prolonged	Speech Disorder Noc Thinking Abnormal Nec	Foreign	Accutane		PS	Roche	ORAL	Dusa Olli	Duration 138
Date: 05/14/1986	ISR Number: 394615-8	Report Type: Expedited	(15-Day)	Company Report Num	er: 860200	518001	Age: 19 YR	Ge	nder: Maje
Outcome	_ <u>PT</u>	Report Source	Product		Role	Manufacturer	-		
Hospitalization - Initial or Prolonged	Amnesia Nec	Foreign	Accutane		PS	Roche	Route	Dose/Unit	Duration
		Health Professional	Alcohol		C	Rodle	ORAL		42
Date: 06/30/1986	ISR Number: 401306-3	Report Type: Expedited (15-Day)	Company Report Numb		760001	Age: 16 YR	Gen	nder: Male
Outcome	<u>PT</u>	Report Source	Product		Role	Manufacturer	=		
Other	Amnesia Nec Conversion Disorder	Health Professional	Accutane		PS	Roche	Route	Dose/Unit	Duration
	Lymphocytosis		Prednisone		c	Rocale	ORAL		159
Date: 07/16/1986	ISR Number: 403506-5	Report Type: Expedited (15-Day)	Company Report Numb	er: 860200	B23001	Age: 18 YR	Gen	der: Male
Outcome	PT	Report Source	Product		ъ.		•		IVIAIC
Hospitalization - Initial or Prolonged	Acne Nos	Health Professional	Accutane		Role PS	Manufacturer	Route	Dose/Unit	Duration
Other	Epistaxis Pharyngitis Nos				rs	Roche	ORAL		417
	Psychotic Disorder Nos								

Date: 08/07/1986	ISR Number: 406042-5 PT	Report Type: Periodic		Company Report Numbe	r: 840200	909001	Age: 20 YR	Ger	ider: Female
Other	Depression Nec	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Headache Nos	Health Professional	Accutane		PS	Roche	ORAL.		492
	Hirsutism								472
	Weight Decreased								
Date: 08/07/1986	ISR Number: 406043-7	Report Type: Periodic		C					·
Outcome	PT			Company Report Numbe	r: 840200	943001	Age: 19 YR	Ger	der: Male
Hospitalization -	Adrenal Insufficiency Nos	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
Initial or Prolonged	Anxiety Nec	Consumer	Асситале		PS	Roche	ORAL		89
	Benign Intracranial								09
	Hypertension Hypotension								
Date: 08/07/1986	ISR Number: 406548-9			- -					
		Report Type: Periodic		Company Report Number	r: 850201	251001	Age: 45 YR	Gen	der: Female
Ontcome	_ <u>PT</u>	Report Source	Product		Role	Manufacturer	Dont		
Other	Depression Nec Emotional Disturbance Nos	Health Professional	Accutane		PS	Roche	ORAL	Dose/Unit	Duration
	Emotional Disturbance Nos		Minocin		c	Made	ORAL		7
Date: 08/01/1986	ISR Number: 406560-X	Report Type: Periodic							
Outcome	PT			Company Report Number	r: 850201	248001	Age: 16 YR	Gen	der: Female
Other	Anaemia Nos	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration .
	Condition Aggravated	Health Professional	Accutane		PS	Roche	ORAL	- 	120
	Depression Nec								120
Date: 08/07/1986	ISR Number: 406570-2	Report Type: Periodic			!				
Outcome	PT	-sopore type. renoule		Company Report Number	860200	213001	Age: 24 YR	Gen	der: Female
Other	Depression Nec	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
		Health Professional	Accutane		PS	Roche	ORAL		146
Date: 08/07/1986	ISR Number: 406581-7	Report Type: Periodic		-					170
Outcome	PT			Company Report Number	850201	180001	Age: 17 YR	Gen	der: Male
Disability	Syncope	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Thinking Abnormal Nec	Health Professional	Accutane		PS	Roche	ORAL	2030 CHIL	133
Date: 08/07/1986	ISR Number: 406588-X						OKAL		133
		Report Type: Periodic		Company Report Number	8402008	375001	Age: 23 YR	Gen	der: Male
Outcome	PT Television N	Report Source	Product		Role	Manufacturer	Donte		
Other	Infection Nos Nail Disorder Nos	Health Professional	Accutane		PS	Roche	Route	Dose/Unit	Duration
	Personality Disorder Nos					TOTHE.	ORAL		112
	,	 							

			3 (4) (4)	Mintermation		atempi e			
Date: 08/07/1986	ISR Number: 406590-8	Report Type: Periodic	1-71	Company Report Number	er: 860200	262001	Age: 57 YR	Ger	der: Male
Outcome	PT	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	T> 41
Other	Nervousness	Health Professional	Accutane		PS	Roche	ORAL	Dosbonit	Duration
Date: 08/07/1986	ISR Number: 407261-4	Report Type: Periodic		Company Report Number	er: 850201	462001	Age: 30 YR		der: Pemale
Outcome	_ PT	Report Source	Product					Gui	der: remaie
Other	Agitation Headache Nos	Consumer	Accutane		Role PS	Manufacturer Roche	Route ORAL	Dose/Unit	Duration 173
	Tachycardia Nos								
Date: 08/07/1986	ISR Number: 407266-3	Report Type: Periodic		Company Report Number	er: 850201	315001	Age: 31 YR	Ger	ider: Male
Outcome	<u>PT</u>	Report Source	Product		Role	Manufacturer	Route	D	D. 4
Other	Impotence	Health Professional	Accutane		PS	Roche	ORAL	Dose/Unit	Duration 51
Date: 08/07/1986	ISR Number: 407270-5	Report Type: Periodic		Company Report Number	er: 850200	849001	Age: 17 YR	Gen	ider: Male
Outcome	PT	Report Source	Product		n.ı.	M		_	
Other	Alopecia Depression Nec Granuloma Nos	Health Professional	Accutane		PS PS	Manufacturer Roche	Route	Dose/Unit	Duration 130
·	Nail Disorder Nos								
Date: 08/07/1986	ISR Number: 407291-2	Report Type: Periodic		Company Report Numbe	er: 860200	187001	Age: 29 YR	Gen	der: Pemale
Outcome	<u>PT</u>	Report Source	Product		Role	Manufacturer	Route	D#1-14	T
Hospitalization - Initial or Prolonged	Depression Nec	Health Professional	Accutane		PS	Roche	ORAL	Dose/Unit	Duration
num of 1 resonged			Lithium		С	Kodio	OKAL,		
			Thorazine		c				
			Xanax		c				
			Aventyl		c		•		
Date: 08/07/1986	ISR Number: 407299-7	Report Type: Periodic		Company Report Number	r: 850200	513001	Age: 19 YR		der: Male
Outcome	PT	Report Source	Product		Role	Manufacturer	D4-		
Other	Impotence	Health Professional	Accutane		PS	Roche	Route	Dose/Unit	Duration
			Theo-Dur		c	Rotte	ORAL		145
			Ventolin		c				
			intal		c				
			Dimetapp		c				

Date: 08/07/1986	ISR Number: 408677-2	Report Type: Periodic		Company Report Number	r- 850200	610001				
Outcome	PT	Report Source	Product			010001	Age: 28 YR	Gen	der: Male	- 1
Other	Dizziness (Exc Vertigo)	Health Professional			Role	Manufacturer	Route	Dose/Unit	Duration	
	Personality Disorder Nos Syncope		Accutane		PS	Roche	ORAL		99	
Date: 07/21/1986	ISR Number: 409013-8	Report Type: Expedited (1	15-Day)	Company Report Numbe	- 860200	852001				
Outcome	PT	Report Source	.	Tany amport than the	1. 000200	933001	Age: 17 YR	Gene	der: Male	
Death	Emotional Disturbance Nos	Consumer	Product		Role	Manufacturer	Route	Dose/Unit	Duration	
	Major Depressive Disorder Nos	Consumer	Accutane		PS	Roche	ORAL			Ì
Date: 08/07/1986	ISR Number: 409359-3	Report Type: Periodic		Company Report Numbe	r: 8502013	352001				
Outcome	PT	Report Source	Product				Age: 17 YR	Gene	der: Male	
Disability	Depression Nec	Health Professional			Role	Manufacturer	Route	Dose/Unit	Duration	
	Personality Disorder Nos	- Total Total Control of	Accutane		PS	Roche	ORAL		4	
Date: 08/07/1986	ISR Number: 409394-5	Report Type: Periodic		Company Report Number	8502009	220001	Age:			
Outcome	PT	Report Source	Product	-			Age.	Geno	der: Male	
Other	Abnormal Dreams	Health Professional	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration	- 1
Date: 08/07/1986	ton at the state of		Accusine		PS	Roche	ORAL		140	
	ISR Number: 410567-6	Report Type: Periodic		Company Report Number	8502005	94001	Age: 21 YR	Gend	der: Male	
Outcome	PT	Report Source	Product		Role	Manufacturer			rest tatate	·
Other	Depression Nec Dermatitis Contact	Consumer	Accutane		PS	Roche	Route	Dose/Unit	Duration	
	Impotence		Minocin		C	Roche	ORAL		231	
	Refractive Errors Nos				C					1
Date: 08/07/1986	ISR Number: 410569-X	Report Type: Periodic		Company Barretty						
Outcome	PT			Company Report Number	: 8502005	85001	Age: 42 YR	Gend	ler: Male	
Other	Abdominal Pain Nos	Report Source	Product		Role	Monufacturer	Route	Dose/Unit	Duration	
	Dyspepsia	Health Professional	Accutane		PS	Roche	ORAL.	Dono Citt	4	-
	Insomnia Nec		Prednisone		С		0.0 12		4	
	Sweating Increased		Keflex		С					
	ISR Number: 410666-9	Report Type: Periodic		Company Report Number	86020000	20001	Age: 28 YR			
Outcome	<u>PT</u>	Report Source	Product	· · · ·			Age: Z8 YR	Gend	er: Female	İ
Other	Anorexia	Health Professional	Accutane		Rele	Manufacturer	Route	Dose/Unit	Duration	
	Condition Aggravated		TYCOUNTE		PS	Roche	ORAL		76	
	Depression Nec Nausca									

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Date: 08/07/1986	ISR Number: 410727-4	Report Type: Periodic		Company Report Number:	8502010	D40001	Age:	Gen	der: Male
Outcome	<u>PT</u>	Report Source	Product				_	0.41	will Male
Other	Major Depressive Disorder Nos	Health Professional	Accutane		S	Manufacturer Roche	Route ORAL	Dose/Unit	Duration
Date: 08/07/1986	ISR Number: 411141-8	Report Type: Periodic		Company Report Number: 8	3502010	258001			<u> </u>
Outcome	PT	Report Source	ъ.	1 -0		350001	Age: 20 YR	Gen	der: Male
Other	Apathy		Product	<u>R</u>	ole	Manufacturer	Route	Dose/Unit	Duration
	Mydriasis	Health Professional	Accutane	P	S	Roche	ORAL		
Date: 08/07/1986	ISR Number: 411260-6	Report Type: Periodic		Company Report Number: 8	502004	177001	Age: 35 YR	· · · · ·	der: Female
Outcome	PT	Report Source	Product				g-: 55 IK	Gel	der: Female
Disability	Condition Aggravated	Health Professional	Accutane		ole	Manufacturer	Route	Dose/Unit	Duration
	Depression Nec Skin Discolouration		Acculance	Pi	S	Roche	ORAL		42
Date: 08/07/1986	ISR Number: 411361-2	Report Type: Periodic		Company Report Number: 8	502006	i55001	Age: 17 YR		der: Male
Outcome	<u>PT</u>	Report Source	Product	_	_		-	-	det. Maje
Disability	Depression Nec	Health Professional	Accutane		ole	Manufacturer	Route	Dose/Unit	Duration
Date: 08/07/1986	IND N A		nomale	PS	š	Roche	ORAL		135
00/07/1980	ISR Number: 411909-8	Report Type: Periodic		Company Report Number: 8	502014	06001	Age: 19 YR	Can	der: Female
Outcome	<u>PT</u>	Report Source	Product				Ber 12 1K	om	der: Female
Other	Conjunctivitis Nec	Health Professional			ole	Manufacturer	Route	Dose/Unit	Duration
	Dysphonia	act t totesatuidi	Accutane	PS	6	Roche	ORAL		102
	Menstrual Disorder Nos								-
Date: 08/07/1986	ISR Number: 413358-5	Report Type: Periodic		Company Report Number: 8	602003	06001	Age: 17 YR		
Outcome	_ PT	Report Source	Product				inge. 1/ IK	Gen	der: Male
Hospitalization -	Blindness Night	Health Professional			ole_	Manufacturer	Route	Dose/Unit	Duration
Initial or Prolonged	Condition Aggravated		Accutane	PS		Roche	ORAL		285
	Hyperlipidaemia Nos		Lithium	C					-
	Mania		Minocin	C				•	
			Tagamet	C					
Date: 08/07/1986	ISR Number: 413372-X	Report Type: Periodic		Company Report Number: 8:	502015	57001	Age: 20 YR	Gene	ler: Female
Outcome	_ <u>PT</u>	Report Source	Product	Re		Manufacture			
Other	Condition Aggravated	Health Professional	Accutane	PS	_	Manufacturer	Route	Dose/Unit	Duration
	Dysphonia Larγngitis Nos			· PS		Roche	ORAL,		115

Depression Nec		Depression Nec	Health Professional	Accutane		PS	Roche	ORAL		48
Depression No. Depr	Outcome	PT Anxiety Nec		Product		Role	Manufacturer		Dose/Unit	Duration
Depression Nec Alcohol C	Date: 07/23/1986	ISR Number: 414343-X	Report Type: Direct		Company Report Numbe	r:		Age: 25 VR		der Formal
Depression Nec				Marax		C				109
Depression Nec Alcohol C	Оша	Deblession Man	Health Professional	Accutane		PS	Roche		3000 CIIII	
Depression Nec Alechol C				Product		Role	Manufacturer	Route	Dose/Unit	Buration
Depression Nec Fieldache Nos Akchol C Company Report Number: 85026077001 Age: 35 YR Gender: Pen			Report Type: Periodic		Company Report Numbe	r: 850201	478001	Age: 34 YR	Gen	der: Female
Depression Nec Alcohol C Company Report Number: 850200707001 Age: 35 YR Gender Fendente Fende			-							
Depression Noc Headache Nos Nausca Date: 08/07/1986 ISR Number: 413453-0 Report Type: Periodic Company Report Number: 8502007/001 Age: 35 YR Gender: Pen Outcome PT Report Source Product Role Manufacturer Route Deserving Depression Noc Mayis Depression Noc Mayis Depression Noc Major Depressive Disorder Nos Health Professional Accutane Product Role Manufacturer Route Deserving Deservi		•	- white Linessions	Accutane		PS	Roche	ORAL		4
Depression Nee	Other	Abdominal Pain Nos					Manufacturer	Route	Dose/Unit	Duration
Detection Noc Headache Nos Nausca Date: 08/07/1986 ISR Number: 413453-0 Report Type: Periodic Company Report Number: 8502007/001 Age: 35 YR Gender: Periodic Outcome PT Report Source Product Role Manufacturer Route Dose/Unit Duration Outcome PT Report Type: Periodic Company Report Number: 860200049001 Age: 18 YR Gender: Mal Outcome PT Report Source Product Role Manufacturer Route Dose/Unit Duration Outcome PT Report Source Product Role Manufacturer Route Dose/Unit Duration Outcome PT Report Source Product Role Manufacturer Route Dose/Unit Duration Outcome PT Report Source Product Role Manufacturer Route Dose/Unit Duration Outcome PT Report Source Product Role Manufacturer Route Dose/Unit Duration Outcome PS Roche ORAL 46 Date: 08/07/1986 ISR Number: 413606-1 Report Type: Periodic Company Report Number: 860200031001 Age: 28 YR Gender: Pen Other Depression Nec Health Professional Accutane PS Roche ORAL 85 Gender: Pen Other Depression Nec Health Professional Accutane PS Roche ORAL 85 Gender: Pen Other Depression Nec Health Professional Accutane PS Roche ORAL 83 Gender: Pen Other Depression Nec Health Professional Accutane PS Roche ORAL 83 Gender: Pen Other Depression Nec Health Professional Accutane PS Roche ORAL 83 Gender: Pen Other Depression Nec Health Professional Accutane PS Roche ORAL 83 Gender: Pen Other Depression Nec Health Professional Accutane PS Roche ORAL 83 Gender: Pen Other Depression Nec Health Professional Accutane PS Roche ORAL 83 Gender: Pen Other Depression Nec Health Professional Accutane PS Roche ORAL 83 Gender: Pen Other Depression Nec Health Professional Accutane PS Roche ORAL 83 Gender: Pen Other Depression Nec Professional Accutane PS Roche ORAL 83 Gender: Pen Other Depression Nec PPS Roche ORAL 83 Gender: Pen Other Depression Nec PPS Roche ORAL 83 Gender: Pen Other Depression Nec PPS Roche ORAL 83 Gender: Pen Other Depression Nec PPS Roche ORAL 83 Gender: Pen Other Depression Nec PPS Roche ORAL 83 Gender: Pen Other Depression Nec PPS Roche ORAL 83 Gender: Pen Other Depression Nec PPS Ro	Outcome	PT	• ••		Company Report Number	ar; 630201.	380001	Age: 22 YR	Gen	der: Female
Dete: 08/07/1986 ISR Number: 413603-6 Report Type: Periodic Company Report Number: 8502007001 Age: 35 YR Gender: Periodic Outcome PT Report Source Product Role Manufacturer PS Roche ORAL Outcome PT Report Source Product Role Manufacturer Role ORAL Accutane PS Roche ORAL Company Report Number: 850200707001 Age: 35 YR Gender: Periodic Positive Adhenia Depression Nec Adhenia Depression Nec Myalgia Date: 08/07/1986 ISR Number: 413603-6 Report Type: Periodic Company Report Number: 860200049001 Age: 18 YR Genter: Mal Outcome PT Report Source Product Role Manufacturer Role ORAL Outcome PT Report Source Product Role Manufacturer Role Dose/Unit Duration Outcome PT Report Source Product Role Manufacturer Role ORAL Outcome PT Report Source Product Role Manufacturer Role ORAL Outcome PT Report Source Product Role Manufacturer Role ORAL Outcome PT Report Source Product Role Manufacturer Role ORAL Outcome PT Report Source Product Role Manufacturer Role ORAL Outcome PT Report Source Product Role Manufacturer Role ORAL Outcome PT Report Source Product Role Manufacturer Role ORAL Outcome PT Report Source Product Role Manufacturer Role ORAL Outcome PT Report Source Product Role Manufacturer Role Dose/Unit Duration Other	Date: 08/07/1986	ISR Number: 413616-4	Report Type: Periodic		Company Denort No. 1	950101				
Dete: 08/07/1986 ISR Number: 413603-6 Report Type: Periodic Company Report Number: 85020070101 Age: 18 YR Gender: Periodic PS Roche ORAL Date: 08/07/1986 ISR Number: 413603-6 Report Type: Periodic Company Report Number: 860200049001 Age: 18 YR Gender: Mal Ontrome PT Report Source Product Role Manufacturer PS Roche ORAL Date: 08/07/1986 ISR Number: 413603-6 Report Type: Periodic Company Report Number: 860200049001 Age: 18 YR Gender: Mal Ontrome PT Report Source Product Role Manufacturer Role Dose/Unit Duration Ontrome PT Report Source Product Role Manufacturer Role Dose/Unit Duration Ontrome PT Report Source Product Role Manufacturer Role Dose/Unit Duration Ontrome PT Report Source Product Role Manufacturer Role Dose/Unit Duration Ontrome PT Report Source Product Role Manufacturer Role ORAL 46 Date: 08/07/1986 ISR Number: 413606-1 Report Type: Periodic Company Report Number: 860200031001 Age: 28 YR Gender: Pan Ontrome PT Report Source Product Role Manufacturer Role ORAL 46	Other	Depression Nec	Health Professional	Accutane					Doseroun	
Date: 08/07/1986 ISR Number: 413603-6 Report Type: Periodic Company Report Number: 86020001001 Age: 35 YR Gender: Periodic Company Report Number: 86020001001 Age: 35 YR Gender: Periodic Dutcome PT Report Source Myalgia Date: 08/07/1986 ISR Number: 413603-6 Report Type: Periodic Company Report Number: 86020001001 Age: 35 YR Gender: Periodic Dutcome PS Roche ORAL Company Report Number: 85020001001 Age: 35 YR Gender: Periodic Dutcome PS Roche ORAL Company Report Number: 86020001001 Age: 18 YR Gender: Mail Dutation Dutcome PS Roche ORAL Date: 08/07/1986 ISR Number: 413603-6 Report Type: Periodic Company Report Number: 86020001001 Age: 18 YR Gender: Periodic Dutcome PS Roche ORAL Date: 08/07/1986 ISR Number: 413606-1 Report Type: Periodic Company Report Number: 860200031001 Age: 28 YR Gender: Periodic Company Report Nu			Report Source	Product	_	Role	Manufacturer	Donte		
Date: 08/07/1986 ISR Number: 413603-6 Report Type: Periodic Company Report Number: 8602000+001 Age: 35 YR Gender: Periodic Company Report Number: 8002000-0001 Age: 35 YR Gender: Periodic Company Report Number: 8502000-0001 Age: 35 YR Gender: Periodic Outcome PT Report Source Product Role Manufacturer Route Dose/Unit Duration Outcome PS Roche ORAL Date: 08/07/1986 ISR Number: 413603-6 Report Type: Periodic Company Report Number: 8602000+9001 Age: 18 YR Gender: Maluforter PC Outcome PT Report Source Product Role Manufacturer Route Dose/Unit Duration Outcome PT Report Source Product Role Manufacturer Route Dose/Unit Duration Outcome PS Roche ORAL		ISR Number: 413606-1	Report Type: Periodic		Company Report Number	er: 860200	031001	Age: 28 YR	Gen	der: Female
Dete: 08/07/1986 ISR Number: 413603-6 Report Type: Periodic Company Report Number: 850200707001 Age: 35 YR Gender: Feriodic Company Report Number: 850200707001 Age: 35 YR Gender: Feriodic Product Role Manufacturer Route Dose/Unit Duration Dutcome PT Report Source Product Role Manufacturer Route Dose/Unit Duration Dutcome PS Roche ORAL Dete: 08/07/1986 ISR Number: 413603-6 Report Type: Periodic Company Report Number: 860200049001 Age: 18 YR Gender: Malor Dottome PT Report Source Product Role Manufacturer Route Dose/Unit Duration Dutcome PT Report Source Product Role Manufacturer Route Dose/Unit Duration Dutcome PT Report Source Product Role Manufacturer Route Dose/Unit Duration Dutcome PT Roche Manufacturer Route Dose/Unit Duration Dur		3	ricalth Professional	Accutane		PS	Roche	ORAL		
Dete: 08/07/1986 ISR Number: 413603-6 Report Type: Periodic Company Report Number: 850200707001 Age: 35 YR Gender: Periodic Company Report Number: 850200707001 Age: 35 YR Gender: Periodic Product Role Manufacturer Route Dose/Unit Duration PS Roche ORAL Company Report Number: 850200707001 Age: 35 YR Gender: Periodic Positive Accutanc PS Roche ORAL Depression Nec Myalgia Dete: 08/07/1986 ISR Number: 413603-6 Report Type: Periodic Company Report Number: 860200049001 Age: 18 YR Gender: Mal						Role	Manufacturer	Route	Dose/Unit	Duration
Dete: 08/07/1986 ISR Number: 413453-0 Report Type: Periodic Company Report Number: 850200707001 Age: 35 YR Gender: Feriodic Office Product Role Manufacturer Route Dose/Unit Duration Office Asthenia Actuans PS Roche ORAL Depression Nec Myalgia					Company Report Number	er: 860200	049001	Age: 18 YR	Ger	ider: Male
Dete: 08/07/1986 ISR Number: 413453-0 Report Type: Periodic Company Report Number: 850200707001 Age: 35 YR Gender: Fear Other Antimuchear Factor Positive Health Professional Accutanc PS Roche ORAL 168	D.4. 08/07/4025	Myalgia			<u> </u>					
Depression Nec Alcohol C Headache Nos Alcohol C Date: 08/07/1986 ISR Number: 413453-0 Report Type: Periodic Company Report Number: 850200707001 Age: 35 YR Gender: For Outcome PT Report Source Product Role Manufacturer Route Dose/Unit Duration Other Antinuclear Factor Positive Health Professional Accurage							E-CARC .	ORAL		
Depression Nec FS Roche ORAL 168 Headache Nos Alcohol C Nausca Date: 08/07/1986 ISR Number: 413453-0 Report Type: Periodic Company Report Number: 850200707001 Age: 35 YR Gender: Pen Outcome PT Report Source Product	Other								Dose/Unit	Duration
Depression Nec PS Roche ORAL 168 Heddache Nos Alcohol C Nausca Date: 08/07/1986 ISR Number: 413453-0 Report Type: Periodic Company Broad Number 85000000000000000000000000000000000000			Report Source	Product		Dolo	Manufacture			
Depression Nec PS Roche ORAL 168 Headache Nos Alcohol C	Date: 08/07/1986	ISR Number: 413453-0	Report Type: Periodic		Company Report Number	er: 850200	707001	Age: 35 YR	Cer	ider: Female
Depression Nec PS Roche ORAL 168				AJCORIO		С				
			TOTAL TOTAL OF	Accutane		PS	Roche	ORAL		168
Other Arthrulgia Health Personal Role Manufacturer Route Dose/Unit Duration							Manufacturer	Route	Dose/Unit	Duration
Ontenne PT -	Outcome		· · · · ·		Company Report Numb	er: 840200	961001	Age: 19 YR	. Ger	ider: Female

Outcome Other Date: 08/07/1986	PT	Report Type: Periodic		Company Report Number	r: 850200	925001	Age: 39 YR		
		Report Source	Product					Ga	der: Female
Date: 08/07/1986	Dysphonia	Health Professional	Accutane		Role PS	Manufacturer Roche	Route	Dose/Unit	Duration
Date: 00/0//1980	IOD N. J. MCC. C.	 				Koche	ORAL		120
	ISR Number: 415015-8	Report Type: Periodic		Company Report Number	r: 850200	985001	Age: 46 YR	Ges	der: Male
Outcome	<u>PT</u>	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
Other	Impotence	Health Professional	Асситале		PS	Roche	ORAL	Dosp.Citit	732
Date: 08/07/1986	ISR Number: 415022-5	Report Type: Periodic		C		·			132
Outcome	PT			Company Report Number	r: 80U2UU	129001	Age:	Gen	der: Female
Other	Amnesia Nec	Report Source Consumer	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Coordination Abnormal Nos	Consumer	Accutane		PS	Roche	ORAL		778
	Urinary Tract Infection Nos Varicose Veins Nos								
Date: 08/07/1986	ISR Number: 415249-2		 -					<u>-</u>	
		Report Type: Periodic		Company Report Number	# 860200	115001	Age: 29 YR	Gen	der: Female
Outcome	Aspartate Aminotransferase	Report Source	Product	<u> </u>	Role	Manufacturer	Route	Dose/Unit	Duration
Omet	Increased	Health Professional	Accutane					22 000 CIA	TATE STORE
					PS	Roche	ORAL		16
	Blood Creatine Phosphokinase Increased		Hydrodiuril		PS C	Roche	ORAL		16
	Increased Blood Lactate Dehydrogenase					Roche	ORAL		16
	Increased					Roche	ORAL		16
Date: 07/28/1986	Increased Blood Lactate Dehydrogenase Increased	Report Type: Periodic		Company	С				16
Date: 07/28/1986 Outcome	Increased Blood Lactate Dehydrogenase Increased Depression Nec ISR Number: 425361-X	Report Type: Periodic	Hydrodiuril	Company Report Number	С		ORAL Age:	Gen	der: Female
	Increased Blood Lactate Dehydrogenase Increased Depression Nec	Report Source	Hydrodiurit	Company Report Number	C : 840201			Gen Dose/Unit	
Outcome Other	Increased Blood Lactate Dehydrogenase Increased Depression Nec ISR Number: 425361-X PT		Hydrodiuril	Company Report Number	C 840201	005003	Age:		der: Female
Outcome Other	Increased Blood Lactate Dehydrogenase Increased Depression Nec ISR Number: 425361-X PT	Report Source	Hydrodiuril Product Accutane	Company Report Number	C 8402010	005003 <u>Manufacturer</u> Roche	Age: Route ORAL	Dose/Unit	der: Female Duration
Outcome Other Date: 11/13/1986 Outcome	Increased Blood Lactate Dehydrogenase Increased Depression Nec ISR Number: 425361-X PT Delirium ISR Number: 430401-8 PT	Report Source Health Professional Report Type: Expedited (15)	Hydrodiuril Product Accutane		C: 840201: Role PS: 860201:	005003 Manufacturer Roche 86001	Age: Route ORAL Age: 19 YR	Dose/Unit Gen	der: Female Duration der: Male
Outcome Other Date: 11/13/1986 Outcome Hospitalization -	Increased Blood Lactate Dehydrogenase Increased Depression Nee ISR Number: 425361-X PT Delitium ISR Number: 430401-8 PT Acne Nos	Report Source Health Professional Report Type: Expedited (15. Report Source	Product Accutane -Day) Product		C: 8402010 Role PS: 8602010	Manufacturer Roche 286001 Manufacturer	Age: Route ORAL Age: 19 YR Route	Dose/Unit	der: Female Duration der: Male Duration
Outcome Other Date: 11/13/1986 Outcome	Increased Blood Lactate Dehydrogenase Increased Depression Nec ISR Number: 425361-X PT Delinium ISR Number: 430401-8 PT Acne Nos Hostility	Report Source Health Professional Report Type: Expedited (15- Report Source Consumer	Product Accutane -Day)		C : 8402011 Role PS : 8602011 Role PS	005003 Manufacturer Roche 86001	Age: Route ORAL Age: 19 YR	Dose/Unit Gen	der: Femile Duration der: Male
Outcome Other Date: 11/13/1986 Outcome Hospitalization - Initial or Prolonged	Increased Blood Lactate Dehydrogenase Increased Depression Nee ISR Number: 425361-X PT Delitium ISR Number: 430401-8 PT Acne Nos	Report Source Health Professional Report Type: Expedited (15: Report Source Consumer	Product Accutane -Day) Product Accutane		C : 8402010 Role PS : 8602010 Role PS C	Manufacturer Roche 286001 Manufacturer	Age: Route ORAL Age: 19 YR Route	Dose/Unit Gen	der: Female Duration der: Male Duration
Outcome Other Date: 11/13/1986 Outcome Hospitalization - Initial or Prolonged	Increased Blood Lactate Dehydrogenase Increased Depression Nec ISR Number: 425361-X PT Delirium ISR Number: 430401-8 PT Acne Nos Hostility Major Depressive Disorder Nos	Report Source Health Professional Report Type: Expedited (15: Report Source Consumer	Product Accutane -Day) Product Accutane Lichiem		C : 8402011 Role PS : 8602011 Role PS	Manufacturer Roche 286001 Manufacturer	Age: Route ORAL Age: 19 YR Route	Dose/Unit Gen	der: Female Duration der: Male Duration

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				II in Correction (Hoper es			
Date: 02/11/1987	ISR Number: 447708-0	Report Type: Expedited	(15-Day)	Company Report Number	860200	086001	Age: 21 YR	Gen	der: Male
Outcome	PT	Report Source	Product		Role	Manufactura	D 4		
Death	Alanine Aminotransferase Increased Back Pain Major Depressive Disorder Nos Personality Disorder Nos	Health Professional	Accutane		PS	Manufacturer Roche	Route ORAL	Dose/Unit	Duration
Date: 02/17/1987	ISR Number: 447722-5	Report Type: Direct	·	Company Report Number:			Age: 22 YR	Gen	ider: Female
Outcome	PT	Report Source	Product		. .		Ť		
Other	Depression Nec Emotional Disturbance Nos	Health Professional	Accutane		Role PS	Manufacturer Roche	Route ORAL	Dose/Unit	Duration 90
Date: 02/05/1987	ISR Number: 448059-0	Report Type: Expedited	(15-Day)	Company Report Number	860200	0952001	Age: 22 YR	Gen	ıder: Male
Outcome	_ <u>PT</u>	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
Other	Cardiovascular Disorder Nos Depression Nec Hypotension Tachycardia Nos	Health Professional	Accutane		PS	Roche	ORAL.	DOSECTION	20
Date: 02/05/1987	ISR Number: 448066-8	Report Type: Expedited	(15-Day)	Company Report Number:	870200	061001	Age: 17 YR	Gen	ider: Maje
Outcome Death	PT Main Daniel Division	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration '
	Major Depressive Disorder Nos	Health Professional	Accutane		PS	Roche	ORAL		94
Date: 02/17/1987	ISR Number: 448219-9	Report Type: Direct		Company Report Number:			Age: 24 YR	Gen	ider: Male
Outcome	_ <u>PT</u>	Report Source	Product		Role	Manufacturer	Route	D	.
Other	Asthenia Depression Nec	Health Professional	Accutane		PS	Roche	ORAL	Dose/Unit	Duration 49
Outcome	ISR Number: 448450-2	Report Type: Expedited	(15-Day)	Company Report Number:	840200	020001	Age: 20 YR	Gen	der: Pemale
Other	PT Calcium Metabolism Disorder	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Major Depressive Disorder Nos Non-Accidental Overdose Tenosynovitis	Health Professional	Accutane		PS	Roche	ORAL		1188
Date: 03/18/1987	ISR Number: 453579-9	Report Type: Expedited ((15-Day)	Company Report Number:	870200	261001	Age: 17 YR	Gen	det: Male
Outcome	_ <u>PT</u>	Report Source	Product	,	Role	Manuel	_		
Death	Cardiac Arrest Chest Pain	Health Professional	Accetane		PS PS	Manufacturer Roche	Route	Dose/Unit	Duration
							ORAL		4

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Date: 04/13/1987 Outcome	ISR Number: 458010-5	Report Type: Expedited	(15-Day)	Company Report Number: 87020	00228001	Age: 17 YR	Gen	der: Male
Other	Conjunctivitis Nec Depression Nec Vasodilatation	Report Source Health Professional	Product Accutance Minocin	Role PS C	Manufacturer Roche	Route ORAL	Dose/Unit	Duration 86
Date: 04/16/1987	ISR Number: 461294-0	Report Type: Expedited	(15-Day)	Company Report Number: 87020	00134001	Age: 18 YR	Gen	der: Male
Outcome Hospitalization - Initial or Prolonged Other	PT Anxiety Nec Epistaxis Headache Nos Major Depressive Disorder Nos	Report Source Health Professional	Product Accutane	Role PS	Manufacturer Roche	Route ORAL	Dose/Unit	Duration 349
Date: 05/12/1987	ISR Number: 462882-8	Report Type: Expedited	(15-Day)	Company Report Number: 86020	00851001	Age: 1 MON	—— Gen	der: Female
Outcome	PT	Report Source	Product	Role	Manufacturer			
Disability Other	Congenital Abnormality Nos Mental Retardation Severity Unspecified	Health Professional	Accutane	PS	Roche	ORAL	Dose/Unit	Duration 144
Date: 05/12/1987	ISR Number: 463495-4	Report Type: Expedited	(15-Day)	Company Report Number: 87020	0501001	Age: 29 YR	Gen	der: Male
Outcome	_ <u>PT </u>	Report Source	Product			-		arr. Mate
Other	Alopecia Depression Nec Hyperlipidaernia Nos Paraesthesia Nec	Health Professional	Accutane	Role PS	Manufacturer Roche	Route	Dose/Unit	Duration 208
Date: 05/22/1987	ISR Number: 464073-3	Report Type: Periodic	-	Company Report Number: 85020	1217001	Age: 15 YR	Gene	der: Malc
Outcome	<u>PT</u>	Report Source	Product	Role	Manufacturer	•		
Death	Major Depressive Disorder Nos	Health Professional	Accutane	PS	Roche	ORAL	Dose/Unit	Duration 30
Onte: 05/08/1987	ISR Number: 465397-6	Report Type: Expedited	(15-Day)	Company Report Number: 87020	0283001	Age: 42 YR	Gene	der: Female
Outcome	_ <u>PT</u>	Report Source	Product	Role	Manufacturer	Route	Desemble	D #
Hospitalization - Initial or Prolonged	Amnesia Nec Coma Nec	Consumer	Accutane	PS	Roche	ORAL	Dose/Unit	Duration
Disability	Dermatitis Nos		Valium	C	-10410	UKAL		
Other	Infection Nos		Nutracort	C				
			Hytone	c				
			Kwell	C				

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			e de deserte	A latomados (FC)) Report			
Date: 06/02/1987	ISR Number: 467421-3	Report Type: Expedited	(15-Day)	Company Report Number: 87020	0301001	Age: 23 YR	Gend	
Outcome	PT	Report Source	Product			Age. 23 IK	Gena	er: Male
Hospitalization -	Hyperlipidaemia Nos	Health Professional	Accutane	Role	Manufacturer	Route	Dose/Unit	Duration
Initial or Prolonged	Joint Disorder Nos			PS	Roche	ORAL		40
Disability	Neurosis Nos	•	Minocin	С				
Other	Oedema Nos							
Date: 07/30/1987	ISR Number: 477054-0	Report Type: Periodic		Company Report Number: 87020	0376001	Age: 18 YR	Gend	er: Male
Outcome	<u>PT</u>	Report Source	Product					Maic
Other	Dry Skin	Health Professional	Accutane	Role	Manufacturer	Route	Dose/Unit_	Duration
	Emotional Disturbance Nos		Accurage	PS PS	Roche	ORAL	,	6
	Epistaxis Face Oedema							
Date: 07/30/1987	ISR Number: 477073-4	Report Type: Periodic		Company Report Number: 87020	0322001	Age: 30 YR	Gend	er: Female
Outcome	PT	Report Source	Product				Guille	. Penale
Hospitalization -	Alopecia	Health Professional	Accutane	Role	Manufacturer	Route	Dose/Unit	Duration
Initial or Prolonged	Condition Aggravated		Acculante	PS	Roche	ORAL		117
	Headache Nos							
	Neurosis Nos							
Date: 07/30/1987	ISR Number: 477424-0	Report Type: Periodic	-	Company Report Number: 86020	0451001	Age: 24 YR	Gende	er: Female
Outcome	PT	Report Source	Product	n-t-				14400
Other	Amnesia Nec	Health Professional	Accutane	Role	Manufacturer	Route	Dose/Unit	Duration
	Confusion		Benzovl Pero	PS	Roche	ORAL		87
	Headache Nos		,					
	Insomnia Nec		Cleocin-T	c				
Date: 07/30/1987	ISR Number: 477426-4	Report Type: Periodic		Company Report Number: 86020	1563001			
Outcome	PT	Damant C		- A A A A A A A A A	7.70.70d1	Age: 42 YR	Gende	er: Male
Other	Anxiety Nec	Report Source Consumer	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Hypercholesterolaemia	Consumer	Accutane	PS	Roche	ORAL,		
	Hypertension Nos		Valium	С				
	Nervousness							
Date: 07/30/1987	ISR Number: 477452-5	Report Type: Periodic		Company Report Number: 860201	212001	Age: 34 YR		
Outcome	PT	Report Source	Product			inger JTIK	Gende	r: Male
Other	Alopecia	Health Professional		Role	Manufacturer	Route	Dose/Unit	Duration
	Depression Nec	sent t totesstonil	Accutane	PS	Roche	ORAL		96
	Headache Nos							

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Date: 07/30/1987	ISR Number: 477703-7								
0-4		Report Type: Periodic		Company Report Number	r: 860201	124001	Age: 22 YR	Gen	der: Female
Outcome Disability	Depression Nec	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
Disability	Keratoconjunctivitis	Health Professional	Accutance		PS	Roche	ORAL		60
Date: 07/30/1987	ISR Number: 477880-8	Report Type: Periodic		Company Report Number	r: 860201	417001	Age: 24 YR		der: Male
Outcome	PT	Report Source	Product				Age. 24 IR	Gal	der: Male
Other	Abnormal Dreams	Consumer	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
	Dry Skin Hepatic Function Abnormal Nos Keratoconjunctivitis		2 Recutant		PS	Roche	ORAL		51
Date: 07/30/1987	ISR Number: 477888-2	Report Type: Periodic		Company Report Number	r: 860201	215001	Age: 25 YR	Gen	der: Female
Outcome	PT	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	D
Other	Personality Disorder Nos	Health Professional	Accutane		PS	Roche	ORAL.	Dose Citt	Duration 60
Date: 07/30/1987	ISR Number: 477889-4	Report Type: Periodic		Company Report Number	m 860201	253001			
Outcome	PT	Report Source	n	7 7 7 7 1	. 000201		Age: 23 YR	Gen	der: Female
Other	Depression Nec	Consumer	Product Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
	Hypertonia		Augmentin		PS	Roche	ORAL		90
	Infection Nos Weight Decreased		Ampicillin		С				
	Wagiii Decivased		Prednisone		c c				
	_		Unipen		c				
Date: 07/30/1987	ISR Number: 478027-4	Report Type: Periodic		Company Report Numbe		dana.	·		
Outcome	PT			ownpany Report Milling	T 8002014	489001	Age: 24 YR	Gen	der: Pemale
Other	Depression Nec	Report Source Health Professional	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Hypercholesterolaemia	i reauti i foressional	Accutane		PS	Roche	ORAL		242
	Keratoconjunctivitis Urticaria Nos								
Date: 07/30/1987	ISR Number: 478209-1	Report Type: Periodic		Company Report Numbe	960201/	244001			
Outcome	PT				. 0002017	299UUI	Age: 19 YR	Gen	der: Male
Other	Abdominal Pain Nos	Report Source Health Professional	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Hyperlipidaemia Nos	A SOUTH PROPERTY OF THE PROPER	Accutane		PS	Roche	ORAL		127
	Palpitations Tachycardia Nos								

		- T	Segren.	e Essint Reporting Of Information de					
Date: 07/30/1987	ISR Number: 478215-7	Report Type: Periodic							
Outcome	DT	·		Company Report Number: 80	502005	568001	Age: 17 YR	Gen	nder: Male
Other	Personality Disorder Nos	Report Source	Product	Ro	le	Manufacturer	Route	Dose/Unit	Duration
- Cuita	r cracitatity Disolder (408	Health Professional	Accutane	PS	_	Roche	ORAL		320
Date: 07/30/1987	ISR Number: 478233-9	Report Type: Periodic	·	Company Report Number: 86	502008	341003	Age;		nder: Male
Outcome	PT	Report Source	Product					Gen	ider: Male
Other	Personality Disorder Nos	Health Professional		Ro	_	Manufacturer	Route	Dose/Unit	Duration
		Taxaar Toresatonar	Accutane	PS		Roche	ORAL		
Date: 07/30/1987	ISR Number: 478255-8	Report Type: Periodic		Company Report Number: 86	502006	511001	Age: 31 YR	Gen	ıder: Malc
Outcome	PT	Report Source	Product	Re		Manufacturer	D		
Other	Alopecia	Health Professional	Accutane	PS	_		Route	Dose/Unit	Duration
	Depression Nec Dry Skin			13		Roche	ORAL		91
	Photosensitivity Reaction Nos								
Date: 07/30/1987									
Date: 0//30/198/	ISR Number: 478260-1	Report Type: Periodic		Company Report Number: 86	502007	714001	Age: 21 YR	Gen	nder: Female
Outcome	<u>PT</u>	Report Source	Product				•		Temple
Other	Depression Nec	Health Professional	Accutane	Ro		Manufacturer	Route	Dose/Unit	Duration
			THEORETE	PS PS		Roche	ORAL.		2
Date: 07/30/1987	ISR Number: 478272-8	Report Type: Periodic		Company Report Number: 87	02001	96001	Age: 48 YR		
Outcome	PT	Report Source				.,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	Age: 40 IK	Gen	ider: Female
Other	Agitation	Health Professional	Product	<u>Ro</u>	le	Manufacturer	Route	Dose/Unit	Duration
	Conjunctivitis Nec	ricalui Professional	Accutane	PS		Roche	ORAL		5
	Headache Nos		Premarin	C					
	Vision Abnormal Nec		Thyroid	С					
Date: 07/30/1987	ISR Number: 478296-0	Report Type: Periodic		Company Report Number: 87	102001	13001			
Outcome	PT	Report Source	n .	y p mitthet; 07	_2001		Age:	Gen	der: Male
	Depression Nec		Product	Ro	le_	Manufacturer	Route	Dose/Unit	Duration
	Personality Disorder Nos	Health Professional	Accutane	PS		Roche			
Date: 07/30/1987	ISR Number: 478847-6	Report Type: Periodic		Company Report Number: 86	02009	99001	Age: 30 YR		
Dutcome	<u>PT</u>	Report Source	Dundant				.age. JUIR	Gen	der: Female
Other	Emotional Disturbance Nos	Health Professional	Product		le_	Manufacturer	Route	Dose/Unit	Duration
	Insomnia Nec	- Total i Total Oligi	Accutane	PS		Roche	ORAL		50
	Unintended Pregnancy								

Date: 07/30/1987	ISR Number: 478852-X	Report Type: Periodic		Company Report Number	er: 860200	906001	Age: 29 YR	Gende	r: Male
Outcome	<u>PT</u>	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
Other	Convulsions Nos Depression Nec	Health Professional	Accutane		PS	Roche	ORAL		
	Headache Nos		Vicodin		C	round,	ORAL		31
	Vomiting Nos		Elavil ·		c				
			Sansert		c				
Date: 07/30/1987	ISR Number: 479438-3	Report Type: Periodic		Company Report Number		102001	Age: 25 YR	Gende	er: Male
Outcome	_ <u>PT</u>	Report Source	Product		Role	Manufacturer	Route	D#1 #	.
Other	Personality Disorder Nos Weight Decreased	Health Professional	Accutane		PS	Roche	ORAL		Duration 88
Date: 07/30/1987	ISR Number: 479450-4	Report Type: Periodic		Company Report Number	er: 860200	993001	Age: 19 YR	Gende	er: Male
Outcome	_ <u>PT</u>	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
Other	Impotence	Health Professional	Accutane		PS	Roche	ORAL		112
Date: 07/30/1987	ISR Number: 479452-8	Report Type: Periodic		Company Report Number	at 860200	986001	Age:	Gende	r: Male
Outcome	<u>PT</u>	Report Source	Product		Role	Manufacturer	Route	D 03. 14	.
Other	Hostility Personality Disorder Nos	Health Professional	Accutane		PS	Roche	ORAL,	Dose/Unit	Duration
Date: 07/30/1987	ISR Number: 479458-9	Report Type: Periodic		Company Report Numbe	r: 860200	958001	Age: 41 YR	Gende	r: Pemale
Outcome	<u>PT</u>	Report Source	Product		ъ.				- I Gilac
Other	Anxiety Nec	Health Professional	Accutane		Role PS	Manufacturer	Route	Dose/Unit	Duration
	Arthralgia		Hydrocortis	One	C	Roche	ORAL		181
	Pruritus Vaginal Discharge		Teldrin	CIL.	c				
Date: 07/30/1987									
	ISR Number: 479466-8	Report Type: Periodic		Company Report Number	r: 860200	411001	Age: 39 YR	Gende	r: Male
Outcome	_ <u>PT</u>	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	D
Other	Alopecia Asthenia	Consumer	Accutane		PS	Roche	ORAL		Duration
	Dry Skin						ORAL	:	23
	Nervousness	•							
Date: 07/30/1987	ISR Number: 479480-2	Report Type: Periodic		Company Report Number	r: 860200	301001	Age: 28 YR	Gende	r: Male
Outcome	<u>PT</u>	Report Source	Product		Dala	Manufactor			
Other	Impotence	Health Professional	Accutane		Role PS	Manufacturer Roche	Route	Dose/Unit 1	Duration

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Date: 08/05/1987	ICD N (COSTS				e a contra a			
	ISR Number: 479575-3	Report Type: Periodic		Company Report Number: 86020	0865001	Age: 16 YR	Gen	der: Male
Outcome	Acne Nos	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Omer	Blood Alkaline Phosphatase Nos Increased Depression Nec Headache Nos	Health Professional	Accutane	PS	Roche	ORAL	Does Cini	44
Date: 07/30/1987	ISR Number: 479590-X	Report Type: Periodic			·			
Outcome	PT			Company Report Number: 860200	9841001	Age:	Gen	der: Unknown
Other	Personality Disorder Nos	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
		Health Professional	Accutane	PS	Roche	ORAL		
Date: 07/30/1987	ISR Number: 479591-1	Report Type: Periodic	· · · ·	Company Report Number: 860200	0841002	Age:	Gen	der: Female
Outcome	<u>PT</u>	Report Source	Product	Role	Manufacturer	- D4		1
Other	Personality Disorder Nos	Health Professional	Accutane	PS	Roche	ORAL	Dose/Unit	Duration
Date: 07/30/1987	ISR Number: 479724-7	Report Type: Periodic		Company Report Number: 860201	189001	Age: 18 YR	Gen	der: Male
Outcome	PT	Report Source	Product	Role	Manufacturer	Done	TS - 277 41	
Other	Depression Nec	Health Professional	Accutane	PS	Roche	Route ORAL	Dose/Unit	Duration 42
Date: 07/30/1987	ISR Number: 479762-4	Report Type: Periodic		Company Report Number: 860200	472001	Age: 37 YR	Gen	der: Pemale
Outcome	PT	Report Source	Product	Role	Manufacturer	D4	.	
Other	Amnesia Nec	Health Professional	Accutane	PS	Roche	ORAL	Dose/Unit	Duration
Date: 07/30/1987	ISR Number: 479763-6	Report Type: Periodic		Company Report Number: 860200		Age: 16 YR		
Outcome	PT	Report Source	Product			Age: 10 YK	Gene	der: Male
Other	Agitation Hostility	Health Professional	Accutane	Role PS	Manufacturer Roche	Route	Dose/Unit	Duration
	Personality Disorder Nos							
Date: 07/30/1987	ISR Number: 479764-8	Report Type: Periodic		Company Report Number: 860200	474001	Age: 36 YR	Gene	der: Female
Outcome	PT	Report Source	Product	Role	Manufacturer	nd		
Other	Depression Nec Emotional Disturbance Nos Insomnia Nec Nervousness	Health Professional	Accutane	PS	Roche	Route	Dose/Unit	Duration 11

				e Elson Reporting St Of Internation (FQ)	eram (1966)			
Date: 07/30/1987	MIDN. A MORNING			44		100		
	ISR Number: 479788-0	Report Type: Periodic		Company Report Number: 87020	0038001	Age: 26 YR	Gender: Male	
Outcome	PT Asthenia	Report Source	Product	Role	Manufacturer	Route		
	Depression Nec Thinking Abnormal Nec	Health Professional	Accutane	PS	Roche	ORAL	Dose/Unit Duration 152	_
Date: 07/30/1987	ISR Number: 479791-0	Report Type: Periodic		Company Report Number: 87020	0049001	Age: 26 YR	Gender: Femal	
Outcome	<u>PT</u>	Report Source	Product	Role	Manufacturer	Route		uc
Other	Depression Nec Keratoconjunctivitis	Health Professional	Accutane	PS	Roche	ORAL	Dose/Unit Duration 103	
Date: 07/27/1987	ISR Number: 481107-0	Report Type: Expedited (15-Day)	Company Report Number: 86020	1428001	Age: 42 YR		
Outcome	<u>PT</u>	Report Source	Product			•	2	AC
Hospitalization - Initial or Prolonged	Coma Nec	Health Professional	Accutane	Role PS	Manufactorer	Route	Dose/Unit Duration	
Disability	Dementia Nos Dermatitis Nos		Valium	rs C	Roche	ORAL		
Other	Sepsis Nos		Nutracort	c				
			Kenalog	c				
			Topicort	c				
Date: 08/18/1987	ISR Number: 481252-X	Report Type: Expedited (15-Day)	Company Report Number: 87020	0889001	Age: 34 YR	Grader: Male	
Outcome	<u>PT</u>	Report Source	Product	Role	Manufacturer	P4		
Hospitalization - Initial or Prolonged	Condition Aggravated Major Depressive Disorder Nos	Health Professional	Accutane		Roche	Route	Dose/Unit Duration	_
Other	Pain Nos		Lithium	C	. Coale	ORAL	327	
	Rhinitis Nos		Capoten	c				
			Navane	\mathbf{c}				
Outcome	ISR Number: 481323-8	Report Type: Periodic		Company Report Number: 860200	0445001	Age: 19 YR	Gender: Male	
Disability	PT Delusion Nos	Report Source	Product	Role	Manufacturer	Route		
Discounty	Parancia Parancia	Health Professional	Accutane	PS	Roche	ORAL	Dose/Unit Duration	-
Oute: 07/30/1987	ISR Number: 481329-9	Report Type: Periodic		Company Report Number: 860200	1413001	Age: 40 YR	Garden V	
Опісоте	PT	Report Source	Product				Gender: Female	le
Other	Cheilitis	Health Professional	Accutane		Manufacturer	Route	Dose/Unit Duration	_
	Condition Aggravated Depression Nec Dry Skin			rs	Roche	ORAL.	140	

			0.000	Event Report Of Information		Report			
Date: 07/30/1987	ISR Number: 481334-2	Report Type: Periodic		Company Report Numb	er: 860200	494001	Age: 39 YR	Gen	der: Male
Опісопіє	_ <u>PT</u>	Report Source	Product		Role	Manufacturer	Route	D #1 11	
Other	Blood Creatine Phosphokinase Increased	Consumer	Accutane		PS	Roche	ORAL	Dose/Unit	Duration
	Influenza Like Illness		Tetracycline	,	C		ORAL		13
	Insomnia Nec								
	Neuritis Nos								
Date: 07/30/1987	ISR Number: 481339-1	Report Type: Periodic		Company Report Number	er 860201	028001	A	- -	
Outcome	PT	Report Source	Dec. Acces			220001	Age:	Gen	der: Male
	Depression Nec	Consumer	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Dry Mouth	~ NIBOTIE!	Accutane		PS	Roche	ORAL		120
	Dry Skin								
	Insomnia Nec								
Date: 07/30/1987	ISR Number: 481388-3	Report Type: Periodic		Company Report Numbe	r: 860200	821001	Age: 20 YR	Gen	dem 341
Outcome	PT	Report Source	Product	·				Gen	der: Male
Other	Dry Skin	Health Professional	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
	Major Depressive Disorder Nos		Acculane		PS	Roche	ORAL		112
	Nausea								
	Non-Accidental Overdose			_					
Date: 07/30/1987	ISR Number: 481442-6	Report Type: Periodic		Company Report Number	× 870200	770001	4		
Outcome	PT	Report Source	.	1,	. 070200	717001	Age: 14 YR	Gene	der: Female
Other	Depression Nec	Health Professional	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Hyperlipidaemia Nos	ricanui Professionai	Accutane	•	PS	Roche	ORAL		155
	Impaired Healing		Prednisone		С				
	Skin Discolouration								
Date: 07/30/1987	ISR Number: 481472-4	Report Type: Periodic		Company Barrelli I					
Outcome	PT			Company Report Numbe	r: 8602014	197001	Age: 23 YR	Geno	der: Male
Hospitalization -	Condition Aggravated	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
Initial or Prolonged	Depression Nec	Health Professional	Accutane		PS	Roche	ORAL		57
Other	Emotional Disturbance Nos						O.O.L		31
	Insomnia Nec								
Date: 07/30/1987	ISR Number: 481595-X	Report Type: Periodic		C					
Outcome	PT			Company Report Number	r: 8602014	62001	Age: 24 YR	Gend	ler: Male
Other	Impotence	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
· ·	····portaile	Health Professional	Accutane		PS	Roche		- Jon Citt	TATE OF

			12.2000	Exent Reporting So Of Information (PC)	Rein (S. 1883) Reiniger			
Date: 07/30/1987	ISR Number: 481669-3	Report Type: Periodic		Company Report Number: 870200	393001	Age: 19 YR	Gen	der: Male
Outcome	PT	Report Source	Product	Role	Manufacturer	ъ.		
Other	Dermatitis Nos	Health Professional	Accutane	PS	Roche	Route	Dose/Unit	Duration
	Dry Skin Palpitations			1.3	rome	ORAL		85
Date: 07/30/1987	ISR Number: 481684-X	Report Type: Periodic		Company Report Number: 860200	539001	Age: 33 YR		
Outcome	_ PT	Report Source	Product	· -		age. 33 IK	Gen	ider: Male
Other	Dysphonia	Health Professional		Role Role	Manufacturer	Route	Dose/Unit	Duration
	Laryngitis Nos	- south a su contribil	Accutane	PS	Roche	ORAL		124
	Rhinitis Nos							
	Simusitis Nos							
Date: 07/30/1987	ISR Number: 481690-5	Report Type: Periodic		Company Report Number: 860200	582001	Age: 16 YR	Gen	der: Malc
Outcome	PT Back Pain	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Back Pain Depression Nec	Health Professional	Accutane	PS	Roche	ORAL.	Post Cult	
Other	Headache Nos		Prednisone	С		OKAL		149
	Hypercholesterolaemia							
Date: 09/21/1987	ISR Number: 488002-1	Daniel To D. V. A		 			 .	
		Report Type: Expedited	(1 3-Day)	Company Report Number: 870200	186001	Age: 44 YR	Gen	der; Female
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	
Other	Anxiety Nec Pruritus	Health Professional	Accutane	PS	Roche		Dose/Unit	Duration
	Skin Discolouration		Tylenol	· c	·sound	ORAL		9
Date: 11/12/1987								
Date: 1111/2/198/	ISR Number: 498538-5	Report Type: Expedited	(15-Day)	Company Report Number: 870201	184001	Age: 36 YR	Gen	der: Male
Outcome	PT	Report Source	Product	***				1,222
Other	Condition Aggravated	Health Professional	Accutane	Role	Manufacturer	Route	Dose/Unit	Duration
	Palpitations		Motrin	PS	Roche	ORAL		45
Date: 11/20/1987	ISR Number: 504235-X	Report Type: Expedited		C Company Report Number: 8702012	204001	A 05 ***		
Outcome	PT	Report Source		, -,p	LOTTO I	Age: 25 YR	Gen	der: Female
Other	Palpitations		Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Supraventricular Tachycardia	Health Professional	Accutane	PS	Roche	ORAL		20
Date: 12/08/1987	ISR Number: 504245-2	Report Type: Expedited (15-Day)	Company Report Number: 8702013	373001	Age: 21 YR	Gen	der: Male
	PT	Report Source	Product	Role	M			Winte
Outcome	- 				Manufacturer	Route	Th (#) **	T
Outcome Other	Acne Nos Dermatitis Nos	Health Professional	Accutane	PS	Roche	ORAL	Dose/Unit	<u>Duration</u>

		1	100000000	Event Reports If information		Report				
Date: 12/28/1987	ISR Number: 504981-8	Report Type: Expedited	(15-Day)	Company Report Number	r: 870201	450001	Age: 18	YR	Ges	ider: Female
Outcome	PT	Report Source	Product		Role	Manufacturer	· · · · · ·			
Other	Major Depressive Disorder Nos	Health Professional	Acculane		PS	Roche	Route ORAL		Oose/Unit	Duration 153
Date: 02/04/1988	ISR Number: 510057-6	Report Type: Expedited	(15-Day)	Company Report Numbe	r: 880200	028001	Age: 25	YR		der: Female
Outcome	PT	Report Source	Product							iuer: remale
Death	Major Depressive Disorder Nos	Health Professional			Role	Manufacturer	Route	3	Dose/Unit	Duration
	Non-Accidental Overdose		Accutane		PS .	Roche	ORAL			5
			Enovid		С					
Data onneuges			Darvocet-N	·	С					
Date: 02/05/1988	ISR Number: 510881-X	Report Type: Expedited	(15-Day)	Company Report Number	r: 880200	030001	Age: 23	YR	Gen	ider: Female
Outcome	PT	Report Source	Product							require
Hospitalization -	Delusion Nos	Health Professional	Accutane		Role	Мапибассытет	Route	<u>I</u>	Dose/Unit	Duration
Initial or Prolonged	Psychotic Disorder Nos	a a a a a a a a a a a a a a a a a a a	Lithobid		PS	Roche	ORAL			3
D-4 04/11/1000			Littioold		С					
Date: 04/11/1988	ISR Number: 516354-2	Report Type: Expedited	(15-Day)	Company Report Numbe	r: 880200	382001	Age: 20	YR	Gen	der: Male
Outcome	PT	Report Source	Product				_			Wale Wale
Hospitalization -	Apathy	Health Professional	Accutane		Role	Manufacturer	Route	<u>1</u>	Dose/Unit	Duration
Initial or Prolonged Other	Hostility		1 account		PS	Roche	ORAL			72
Ouler	Paranoia									
Date: 04/06/1988	ISR Number: 517122-8	Report Type: Expedited	(15-Day)	Company Report Numbe	r: 870200;	281001	Age: 18	YR	Gen	der: Male
Outcome	PT	Report Source	Product		Role	Managarta				
Hospitalization	Epistaxis	Health Professional	Accutane		PS	Manufacturer	Route	<u>I</u>	Dose/Unit	Duration
Initial or Prolonged	Headache Nos				1.0	Roche	ORAL			350
	Major Depressive Disorder Nos		·							
Date: 07/06/1988	ISR Number: 530830-8	Report Type: Expedited	(15-Day)	Company Report Number	r: 880200	786001	A	VD.		
Outcome	PT			2>F-24.44000c			Age: 16	YR	Gen	der: Male
Death	Major Depressive Disorder Nos	Report Source	Product		Role	Manufacturer	Route	r	ose/Unit	Duration
		Health Professional	Accutane		PS	Roche	ORAL.			100
Date: 07/06/1988	ISR Number: 531912-7	Report Type: Expedited	(15-Day)	Company Report Number	r: 8801005	84001		YR	Gen	
Outcome	<u>PT</u>	Report Source	Product				Ü			Mutc
Hospitalization -	Abnormal Dreams	Foreign	Accutane		Role	Manufacturer	Route		lose/Unit	Duration
Initial or Prolonged		Health Professional	Accurage		PS	Roche	ORAL			14

Impotence			LIM		i Even Report		ang (ang)			
Outcome	te: 07/30/1987	ISR Number: 532010.0			(2/31/0)+02000	(61/08)	i Kepart	ji ji		
Manufacturer Moure Mount			Report Type: Periodic		Company Report Number	r: 850200	00985001	Age: 46 YR	Gen	der: Male
Health Professional Accutance PS Roche ORAL				Product		Role	Manufacturer	Powte	D 03-14	
Date: 08/03/1988 ISR Number: 535046-7 Report Type: Expedited (15-Day) Company Report Number: 850101548001 Age: 22 YR Gends Outcome PT Report Source Product Role Manufacturer Route Deserting PS Roche ORAL Dete: 08/17/1988 ISR Number: 537031-8 Report Type: Expedited (15-Day) Company Report Number: 880200890001 Age: 39 YR Gends Outcome PT Report Source Product Role Manufacturer Route Deserting PS Roche ORAL Dete: 08/19/1988 ISR Number: 537742-4 Report Type: Periodic Company Report Number: 870201546001 Age: 16 YR Gends Outcome PT Report Source Product Role Manufacturer Route Deserting PS Roche ORAL Dete: 08/19/1988 ISR Number: 537742-4 Report Type: Periodic Company Report Number: 870201546001 Age: 16 YR Gends Outcome PT Report Source Product Role Manufacturer Route Deserting PS Roche ORAL Depression Noc Dry Skin Report Source Product Role Manufacturer Route Deserting PS Roche ORAL Depression Noc Dry Skin Report Source Product Role Manufacturer Route Deserting PS Roche ORAL Detection Report Source Product Role Manufacturer Route Deserting PS Roche ORAL Detection Report Source Product Role Manufacturer Route Deserting Report Number: 87020151001 Age: 18 YR Gends Outcome PS Report Source Product Role Manufacturer Route Deserting Report Number: 870201511001 Age: 18 YR Gends Outcome Dry Skin Report Source Product Role Manufacturer Route Deserting Report Number: 870201511001 Age: 18 YR Gends Outcome Role Manufacturer Route Deserting Report Number: 870201511001 Age: 18 YR Gends Outcome Role Manufacturer Route Deserting Report Number: 870201511001 Age: 18 YR Gends Outcome Role Role Manufacturer Route Deserting Report Number: 870201511001 Age: 39 YR Gends Outcome Role Role Manufacturer Route Deserting Report Number: 870201517001 Age: 39 YR Gends Outcome Role Role Report Report Number: 870201517001 Age: 39 YR Gends Outcome Role Role Report Report Number: 870201517001 Age: 39 YR Gends Outcome Role Report Report Role Report Ro			Health Professional	Accutane					Dose Chit	Duration 1095
Outcome PT Report Source Product Role Manufacturer Route Dose/Unit Professional Product Product Professional Provided Professional Prof	e: 08/03/1988	ISR Number: 535046-7	Report Type: Expedited	(15-Day)	Company Report Number	r: 850101	548001			
Hospitalization Dry Mouth Hospitalization Dry Mouth Health Professional Foreign Accutane PS Roche ORAL Histilian or Prolonged Historian Nos Psychotic Disorder Nos Date: 08/17/1988 ISR Number: 537031-8 Report Type: Expedited (15-Day) Company Report Number: 880200890001 Agr: 39 YR Gende Outcome PT Report Source Product Role Manufacturer Route DeserVinit Professional Accutane PS Roche ORAL Deservation Nos Hypothyroidism Joint Disorder Nos Date: 08/19/1988 ISR Number: 537742-4 Report Type: Periodic Company Report Number: 870201546001 Agr: 16 YR Gende Outcome PT Report Source Product Role Manufacturer Route DoserVinit Agril 18 YR Gende Outcome PT Report Source Product Role Manufacturer Route DoserVinit Agril 18 YR Gende Outcome PT Report Source Product Role Manufacturer Route DoserVinit Depression Nos Dry Skin Disorder Nos Dry Skin Report Type: Periodic Company Report Number: 870201531001 Agr: 18 YR Gende Outcome PT Report Source Product Role Manufacturer Route DoserVinit Depression Nos Dry Skin Report Type: Periodic Company Report Number: 870201531001 Agr: 18 YR Gende Outcome PT Report Source Product Role Manufacturer Route DoserVinit Deservation Agril 18 YR Gende Outcome PT Report Source Product Role Manufacturer Route DoserVinit Deservation Agril 18 YR Gende Outcome PT Report Source Product Role Manufacturer Route DoserVinit Deservation Agril 18 YR Gende Outcome PT Report Source Product Role Manufacturer Route DoserVinit Deservation Agril 18 YR Gende Outcome PT Report Source Product Role Manufacturer Route DoserVinit Deservation Agril 18 YR Gende Outcome PT Report Source Product Role Manufacturer Route DoserVinit Deservation Role Route DoserVinit Deservation Role Route Role Role Manufacturer Route DoserVinit Deservation Role Role Role Role Role Role Role Role			Report Source	Product				•	Gai	der: Female
Health Professional Accutanc Product Role Health Professional Accutanc Product Hopitalization. Initial or Protonged Other Hypophycaemia Nos Hypophycaemia Nos Hypophycaemia Nos Health Professional Accutanc Product Report Type: Periodic Company Report Number: 870201546001 Age: 16 YR Gende Other Amnesia Noc Amesia Noc Health Professional Accutanc Product Role Manufacturer Route Dose/Unit Other Amnesia Noc Apathy Depression Noc Dry Skin Depression Noc Dry Skin Depression Noc Dry Skin Detection Office of the Professional Accutanc Product Company Report Number: 870201531001 Age: 18 YR Gende Other Abhormal Dreams Health Professional Accutanc Product Role Manufacturer Route Dose/Unit Dose/Unit Report Type: Periodic Company Report Number: 870201531001 Age: 18 YR Gende Other Abhormal Dreams Health Professional Accutanc Product Role Manufacturer Route Dose/Unit Report Type: Periodic Company Report Number: 870201531001 Age: 18 YR Gende Other Dider Abhormal Dreams Health Professional Accutanc Product Role Manufacturer Route Dose/Unit Report Type: Periodic Company Report Number: 870201531001 Age: 18 YR Gende Other Other Abhormal Dreams Health Professional Accutanc Product Role Manufacturer Route Dose/Unit Report Source Product Company Report Number: 870201531001 Age: 39 YR Gende Other Report Source Product Convalisions Nos Report Type: Periodic Company Report Number: 870201517001 Age: 39 YR Gende		•							Dose/Unit	Duration
Date: 08/17/1988 ISR Number: 537/31-8 Report Type: Expedited (15-Day) Company Report Number: 880200890001 Age: 39 YR Gende Obtrome PT Report Source Product Role Manufacturer Route Dose/Unit Initial or Prolonged Hypoglycaemia Nos Health Professional Accutanc PS Roche ORAL Accutanc Obtrome PT Report Source Product Company Report Number: 870201546001 Age: 16 YR Gende Obtrome PT Report Source Product Role Manufacturer Route Dose/Unit Dose/Unit Professional Accutanc PS Roche ORAL Degression Nec Dry Skin Date: 08/19/1988 ISR Number: 537746-1 Report Type: Periodic Company Report Number: 870201531001 Age: 18 YR Gende Obtrome PT Report Source Product Role Manufacturer Route Dose/Unit Obtrome PT Report Source Product Role Manufacturer Route Dose/Unit Obtrome PT Report Source Product Role Manufacturer Route Dose/Unit Obtrome PT Report Source Product Role Manufacturer Route Dose/Unit Obtrome PT Report Source Product Role Manufacturer Route Dose/Unit Dose/Unit Obtrome PT Report Source Product Role Manufacturer Route Dose/Unit Dose	er v rorong col		Health Professional			rs	Koche	ORAL		17
Date: 08/17/1988 ISR Number: 537031-8 Report Type: Expedited (15-Day) Company Report Number: 880200890001 Age: 39 YR Gender Outcome PT Report Source Product Role Manufacturer Route Dese/Unit Accutance PS Roche ORAL Health Professional Accutance PS Roche ORAL Figure 1										
Outcome PT Report Source Product Role Manufacturer Route DescUnit Other Str. 1987 Str.	e: 08/17/1988		Report Types By 2013	25.0						
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Hypothyridism Joint Disorder Nos Date: 08/19/1988 ISR Number: 537742-4 Report Type: Periodic Company Report Number: 870201546001 Age: 16 YR Gende Outcome PT Report Source Product Role Manufacturer Route Dose/Unit Depression Nec Dry Skin Date: 08/19/1988 ISR Number: 537746-1 Report Type: Periodic Company Report Number: 870201531001 Age: 18 YR Gende Outcome PT Report Source Product Role Manufacturer Route Dose/Unit Dose/	ial or Prolonged		Health Professional	Accutane		PS	Roche		Descript	462
Date: 08/19/1988 ISR Number: 537742-4 Report Type: Periodic Company Report Number: 870201546001 Age: 16 YR Gende Other Annesia Nec Health Professional Accutane PS Roche ORAL Date: 08/19/1988 ISR Number: 537746-1 Report Type: Periodic Company Report Number: 870201531001 Age: 18 YR Gende Outcome PT Report Source Product Role Manufacturer Route Dose/Unit PS Roche Other Abnormal Dreams Health Professional Accutane PS Roche ORAL Decutation Age: 18 YR Gende Other Conficient Age: 18 YR Gende Other Company Report Number: 870201531001 Age: 18 YR Gende Other Conficient Age: 39 YR Gende	er er							VIII.		402
Outcome PT Report Type: Periodic Company Report Number: 870201546001 Age: 16 YR Gende Outcome PT Report Source Product Role Manufacturer Route Dose/Unit Depression Nec Apathy Depression Nec Dry Skin Date: 08/19/1988 ISR Number: 537746-1 Report Type: Periodic Company Report Number: 870201531001 Age: 18 YR Gende Outcome PT Report Source Product Role Manufacturer Route Dose/Unit Dose/Un	:: 08/19/1988		 							
Other Amnesia Nec Apathy Health Professional Accutane PS Roche ORAL Depression Nec Dry Skin Date: 08/19/1988 ISR Number: 537746-1 Report Source Product Role Manufacturer Route Dose/Unit Other Abnormal Dreams Health Professional Accutane PS Roche ORAL Condition Aggravated Convulsions Nos Date: 08/19/1988 ISR Number: 537750-3 Report Type: Periodic Company Report Number: 870201531001 Age: 18 YR Gende ORAL Condition Aggravated Convulsions Nos Date: 08/19/1988 ISR Number: 537750-3 Report Type: Periodic Company Report Number: 870201517001 Age: 39 YR Gende Outcome PT Report Source Product Date Manufacturer Route Dose/Unit Date Outcome PT Report Source Product Date Outcome PT Report Source Product Date Manufacturer Route Dose/Unit Date Outcome PT Report Source Product Date Outcome PT Report Source Product Date Outcome PT Report Source Product Date Outcome PD Report Source PD Report Sou	_		Report Type: Periodic		Company Report Numbe	r: 870201	546001	Age: 16 YR	Gene	der: Male
Apathy Depression Nec Dry Skin Date: 08/19/1988 ISR Number: 537746-1 Report Type: Periodic Company Report Number: 870201531001 Age: 18 YR Gende Outcome PT Report Source Product Role Manufacturer Route Dose/Unit Date: Back Pain Condition Aggravated Convulsions Nos Pate: 08/19/1988 ISR Number: 537750-3 Report Type: Periodic Company Report Number: 870201531001 Age: 39 YR Gende Outcome PT Report Source Product Role Manufacturer Route Dose/Unit Date: 08/19/1988 ISR Number: 537750-3 Report Type: Periodic Company Report Number: 870201517001 Age: 39 YR Gende			Report Source	Product		Role	Manufacture	TD .		
Depression Nec Dry Skin Date: 08/19/1988 ISR Number: 537746-1 Report Type: Periodic Company Report Number: 870201531001 Age: 18 YR Gende Outcome PT Report Source Product Role Manufacturer Route Dose/Unit Depressional Accutance PS Roche ORAL Condition Aggravated Convulsions Nos Date: 08/19/1988 ISR Number: 537750-3 Report Type: Periodic Company Report Number: 870201517001 Age: 39 YR Gende Outcome PT Report Source Product Date Manufacturer Route Date Manufacturer Route Date Oracle Ora	er .		Health Professional	Accutane					Dose/Unit	Duration
Date: 08/19/1988 ISR Number: 537746-1 Report Type: Periodic Company Report Number: 870201531001 Age: 18 YR Gende Outcome PT Report Source Product Role Manufacturer Route Dose/Unit Date PS Roche ORAL Condition Aggravated Convulsions Nos Date: 08/19/1988 ISR Number: 537750-3 Report Type: Periodic Company Report Number: 870201517001 Age: 39 YR Gende Outcome PT Report Source Product Date Manufacturer Route Date Date Date Date Date Date Date Da							Roda	ORAL		134
Outcome PT Report Type: Periodic Company Report Number: 870201531001 Age: 18 YR Gende Outcome PT Report Source Product Role Manufacturer Route Dose/Unit 1 Abnormal Dreams Back Pain Condition Aggravated Convulsions Nos Date: 08/19/1988 ISR Number: 537750-3 Report Type: Periodic Company Report Number: 870201517001 Age: 39 YR Gende Outcome PT Report Source Product Date Manufacturer Route Date Manufacturer Route Dose/Unit 1 Outcome PT Report Source Product Date Manufacturer Route Date Manufacturer Route Dose/Unit 1 Outcome PT Report Source Product Date Manufacturer Route Date Manufacturer Route Dose/Unit 1 Outcome PT Report Source Product Date Manufacturer Route Date Manufacturer Route Dose/Unit 1 Outcome PT Report Source Product Date Manufacturer Route Date Manufacturer Route Dose/Unit 1 Outcome PT Report Source Product Date Manufacturer Route Dose/Unit 1 Outcome PT Report Source Product Date Manufacturer Route Dose/Unit 1 Outcome PT Report Source Product Date Manufacturer Route Dose/Unit 1 Outcome PT Report Source Product Date Manufacturer Route Dose/Unit 1 Outcome PT Report Source Product Date Manufacturer Route Dose/Unit 1 Outcome PT Report Source Product Date Manufacturer Route Dose/Unit 1 Outcome PT Report Source Product Date Manufacturer Route Dose/Unit 1 Outcome PT Report Source Product Date Manufacturer Route Dose/Unit 1 Outcome PT Report Source Product Date Manufacturer Route Dose/Unit 1 Outcome PT Report Source Product Date Manufacturer Route Dose/Unit 1 Outcome PT Report Source Product Date Manufacturer Route Dose/Unit 1 Outcome PT Report Source Product Date Manufacturer Route Dose/Unit 1 Outcome PT Report Source Product Date Manufacturer Route Dose/Unit 1 Outcome PT Report Source Product Date Manufacturer Route Dose/Unit 1 Outcome PT Report Source PT Route Date Manufacturer Route Dose/Unit 1 Outcome PT Report Source PT Route Date Manufacturer Route Dose/Unit 1 Outcome PT Route Date Manufacturer Route Dose/Unit 1 Outcome PT Route Date Manufacturer Route Dose/Unit 1 Outcome PT Ro		Dry Skin					•			
Outcome PT Report Source Product Role Manufacturer Route Dose/Unit Defect Officer Abnormal Dreams Back Pain Back Pain Health Professional Accutane PS Roche ORAL Condition Aggravated Conduction Source Convalsions Nos sate: 08/19/1988 ISR Number: 537750-3 Report Type: Periodic Company Report Number: 870201517001 Age: 39 YR Gende	: 08/19/1988 I	SR Number: 537746-1	Report Type: Periodic		Company Barret N	07000:				
Other Abnormal Dreams Health Professional Accutane PS Roche ORAL Condition Aggravated Convulsions Nos ste: 08/19/1988 ISR Number: 537750-3 Report Type: Periodic Company Report Number: 870201517001 Age: 39 YR Gende	come	PT			company кереп Number	* 8/0201	531001	Age: 18 YR	Gene	ler: Male
Back Pain Accutane PS Roche ORAL Condition Aggravated Convulsions Nos ste: 08/19/1988 ISR Number: 537750-3 Report Type: Periodic Company Report Number: 870201517001 Age: 39 YR Gende						Role	Manufacturer	Route	Dose/Unit	Duration
Condition Aggravated Convulsions Nos lete: 08/19/1988 ISR Number: 537750-3 Report Type: Periodic Company Report Number: 870201517001 Age: 39 YR Gende Outcome PT Report Source Product			1 cauti Professional	Accutane		PS	Roche	ORAL		163
ole: 08/19/1988 ISR Number: 537750-3 Report Type: Periodic Company Report Number: 870201517001 Age: 39 YR Gende Outcome PT Report Source Product										
Report Type: Periodic Company Report Number: 870201517001 Age: 39 YR Gende Outcome PT Report Source Product Product	D8/19/1088									
Datcome PT Report Source Product		ok Number: 537750-3	Report Type: Periodic		Company Report Number	870201	517001	Age: 39 YR	G-d	ler: Female
			Report Source	Product		ъ.	37		Gaid	remale
	r	Depression Nec				Role	Manufacturer	Route	Dose/Unit	Duration

			estini.	e Essent Reporti Of Information		Report			
Date: 08/19/1988	ISR Number: 537756-4	Report Type: Periodic		Company Report Numbe	r: 870201	484001	Age: 19 YR	Ger	nder: Female
Outcome	PT	Report Source	Product		Role	Manufacturer			ider. Temaje
Other	Palpitations	Health Professional	Accutane		PS	Roche	ORAL	Dose/Unit	Duration 33
Date: 08/19/1988	ISR Number: 538134-4	Report Type: Periodic		Company Report Numbe	r: 870201	198001	Age: 40 YR		
Outcome	PT	Report Source	Product				Age: 401K	Gen	ider: Female
Other	Asthenia	Health Professional			Role	Manufacturer	Route	Dose/Unit	Duration
	Influenza Like Illness Thinking Abnormal Nec	Treath (Toressonal	Accutane		PS	Roche	ORAL		7
Date: 08/19/1988	ISR Number: 538137-X	Report Type: Periodic		Company Report Numbe	r: 870201	207001	Age: 20 YR	Gen	ıder: Male
Outcome	PT	Report Source	Product		Dal.				Walt
Other	Abnormal Dreams	Health Professional	Accutane		Role PS	Manufacturer	Route	Dose/Unit	Duration
Date: 08/19/1988	ISR Number: 538138-1	Report Type: Periodic		Company Report Numbe		Roche	ORAL,		120
Outcome	PT	Domest C		-Land makers tanning	0/0201.	LUUUUI	Age: 32 YR	Gen	der: Male
Other	Abnormal Dreams	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Depression Nec Emotional Disturbance Nos	Health Professional	Accutane		PS	Roche	ORAL		127
Date: 08/19/1988	ISR Number: 538140-X	Report Type: Periodic	·	Company Report Numbe	r: 8702014	120001	Age: 18 YR	Gen	der: Female
Outcome	PT	Report Source	Product		D.J.	X			er. remie
Other	Alopecia	Consumer	Accutane		Role PS	Manufacturer	Route	Dose/Unit	Duration
	Amenorrhoea Nos Depression Nec Skin Discolouration				гъ	Roche	ORAL		144
Date: 08/19/1988	ISR Number: 538142-3	Report Type: Periodic		Company Report Number	8702014	155001	Age: 21 YR		
Outcome	_ PT	Report Source	Product	-			g 211K	Gen	der: Male
Other	Blood Alkaline Phosphatase Nos	Health Professional	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
	Increased Condition Aggravated Hostility Personality Disorder Nos	- WA A AND RAPPELYSISSE	Accurane		PS	Roche	ORAL		71
Date: 08/19/1988	ISR Number: 538950-9	Report Type: Periodic		Company Report Number	: 8702004	85001	Age: 18 YR		
Outcome	PT	Report Source	Decidend				Age: 18 YR	Gene	der: Female
Other	Depression Nec	Consumer	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Emotional Disturbance Nos	CONSTITUTE	Accutane		PS	Roche	ORAL		103

		100		e Event Reports Of Information		Same (\$10.185)			
						341311111			
Date: 08/19/1988	ISR Number: 538951-0	Report Type: Periodic		Company Report Number	r: 870200	482001	Age: 17 YR	Gen	der: Male
Outcome	<u>PT</u>	Report Source	Product		D-1.	Wt			
Other	Emotional Disturbance Nos Major Depressive Disorder Nos	Health Professional	Accutane		Role PS	Manufacturer Roche	Route ORAL	Dose/Unit	Duration 50
Date: 08/19/1988	ISR Number: 538953-4	Report Type: Periodic		Company Report Numbe	r: 870200	529001	Age: 39 YR	Gen	der: Female
Outcome	<u>PT</u>	Report Source	Product				-	04	mer. remaie
Other	Cataract Nec	Health Professional	Accutane		Role_	Manufacturer	Route	Dose/Unit	Duration
	Nervousness Vasodilatation		recutanc		PS	Roche	ORAL		156
Date: 08/19/1988	ISR Number: 538959-5	Report Type: Periodic		Company Report Numbe	r: 870200	510001	Age: 16 YR	Gen	der: Female
Outcome	PT	Report Source	Product		Role	Manufacturer	Dt.		
Other	Breast Neoplasm Nos Personality Disorder Nos	Health Professional	Accutane		PS	Roche	Route	Dose/Unit	Duration 518
Date: 08/19/1988	ISR Number: 538962-5	Report Type: Periodic		Company Report Number	r: 870200	895001	Age: 27 YR	Gen	der: Female
Outcome	PT	Report Source	Product		Role	Manufacturer	Route	D #1.0	_
Other	Acne Nos Depression Nec Dysmenorrhoca	Health Professional	Accutane		PS	Roche	ORAL	Dose/Unit	Duration 102
Date: 08/19/1988	Keratoconjunctivitis						_		
	ISR Number: 539000-0	Report Type: Periodic		Company Report Number	r: 870200	639001	Age: 25 YR	Gen	der: Female
Outcome	_ PT	Report Source	Product		Role	Manufacturer	. .		
Disability	Asthenia Depression Nec	Health Professional	Accutane		PS	Roche	Route ORAL	Dose/Unit_	Duration 135
Date: 08/19/1988	ISR Number: 539130-3	Report Type: Periodic		Company Report Number	880200	107001	Age: 17 YR	Gen	der: Male
Outcome	<u>PT</u>	Report Source	Product		Role	Manufacturer	Done		
Other	Depression Nec Influenza Like Illness	Health Professional	Accutane		PS	Roche	Route ORAL	Dose/Unit	Duration
	Weight Decreased								
Date: 08/19/1988	ISR Number: 539170-4	Report Type: Periodic		Company Report Number	: 870200	301001	Age: 35 YR	Gene	der: Female
Outcome	PT Patricia	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Dun-41
Other	Palpitations	Health Professional	Accutane		PS	Roche	ORAL	TARRE CHIL	Duration
			Retin-A		c		UKAL,		29

	4	TIA 1	0.00000	Event Reports If Information		Report			
Date: 08/19/1988	ISR Number: 539181-9	Report Type: Periodic		Company Report Numbe	r: 870200	0652001	Age: 43 YR	Ger	der: Female
Outcome	<u>PT</u>	Report Source	Product		Role	Manufacturer			
Other	Condition Aggravated	Health Professional	Accutane		PS	Roche	Route	Dose/Unit	Duration
	Emotional Disturbance Nos Hypercholesterolaemia		Seldane		C	ROCHE	ORAL		157
	Leucopenia Nos								
Date: 08/19/1988	ISR Number: 539201-1	Report Type: Periodic		-					
Outcome	PT	·-		Company Report Number	: 880200	266001	Age: 16 YR	Gen	der: Male
Other	Anaemia Nos	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Blood Lactate Dehydrogenase	Health Professional	Accutane		PS	Roche	ORAL		50
	Increased Insomnia Nec		Erythromycin		C				30
Date: 08/19/1988	ISR Number: 539239-4	Report Type: Periodic		Company Report Number	- 880200	M1001		 -	
Outcome	PT	Report Source		1 - y	. 000200	041001	Age: 34 YR	Gen	der: Female
Other	Emotional Disturbance Nos	Health Professional	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Headache Nos	Andrea Potosicia	Accutane		PS	Roche	ORAL		67
	Paraesthesia Nec								
Date: 08/19/1988	ISR Number: 539417-4	Report Type: Periodic		Company Report Number	870200	947001	Age: 28 YR		
Outcome	PT	Report Source	Product	· -			Age. 20 1 K	Gen	der: Female
Other	Abnormal Dreams	Health Professional	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
	Amnesia Nec Benign Intracranial		Aspirin		PS C	Roche	ORAL		121
	Hypertension				C				
	Vertigo Nec								
Date: 08/19/1988	ISR Number: 539442-3	Report Type: Periodic		Company Report Number	970201	166001			
Outcome	PT	Report Source			. 070201.	10001	Age: 24 YR	Gen	der: Male
Other	Condition Aggravated	Health Professional	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Depression Nec		Accutane		PS	Roche	ORAL	_	
Date: 08/19/1988	ISR Number: 539447-2	Report Type: Periodic		Company Report Number	8702011	15001	Age: 37 YR		1
Outcome	PT	Report Source	Product	-				Gene	ler: Female
Other	Cough	Health Professional	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
	Dysphonia		· seconarie		PS	Roche	ORAL		126

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Date: 08/19/1988	ISR Number: 539456-3	Report Type: Periodic		Company Report Numb	er: 870201	159001	Age: 15 YR	Gen	der: Male
Outcome	_ PT	Report Source	Product				•		der, Maje
Other	Acne Nos	Health Professional	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
	Depression Nec		According		PS	Roche	ORAL		153
	Insomnia Nec			_					
Date: 08/19/1988	ISR Number: 539713-0	Report Type: Periodic		Company Report Numb	er: 870201	075001	Age: 35 YR	C-	der: Female
Outcome	PT	Report Source	Product				age. 33 IK	Gen	der: Female
Other	Depression Nec	Health Professional			Role	Manufacturer	Route	Dose/Unit	Duration
	Libido Decreased		Accutane		PS	Roche	ORAL		145
Date: 08/19/1988	ISR Number: 539812-3	Report Type: Periodic		Company Report Numb	87(Y)00	617001	4 123		
Outcome	PT	Danast Causes	D	Spend supercratifi		01,001	Age: 17 YR	Gen	der: Female
Other	Bronchitis Nos	Report Source Health Professional	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Dry Skin	reatur Professional	Accutane		PS	Roche	ORAL		154
	Personality Disorder Nos								
	Urinary Tract Infection Nos								
Date: 08/19/1988	ISR Number: 539821-4	Report Type: Periodic		Company Report Numb	er: 870200	543001	Age: 15 YR		der: Male
Outcome	PT	Report Source	Product	•					uer. Male
Hospitalization -	Depression Nec	Health Professional	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
Initial or Prolonged Other	Hepatic Function Abnormal Nos		Mellaril		PS	Roche	ORAL		29
Oule	Hostility		Sinequan		c				
	Hyperoricaeznia		Smeduan	· · · · · · · · · · · · · · · · ·	С				
Date: 08/19/1988	ISR Number: 540162-X	Report Type: Periodic		Company Report Numb	er: 870200	508001	Age: 17 YR	Com	der: Male
Outcome	PT	Report Source	Product		D-3-	No			
Other	Personality Disorder Nos	Health Professional	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
			- According		PS	Roche	ORAL		56
Date: 08/19/1988	ISR Number: 541346-7	Report Type: Periodic		Company Report Numb	er: 880200	139001	Age: 20 YR	Cen	der: Male
Outcome	PT	Report Source	Product	-			_	Juli	uer. Maic
Other	Amnesia Nec	Health Professional	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
	Condition Aggravated		Accidance		PS	Roche	ORAL		135
Date: 08/19/1988	ISR Number: 541353-4	Report Type: Periodic		Company Report Numb	*** 88U3U0	167001			
Outcome	PT	Report Source	ъ .		es. 000200.		Age:	Gen	der: Female
	Alopecia	Consumer	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Condition Aggravated	Consumer	Accutane		PS	Roche	ORAL		119
	Depression Nec		Parnate		C				•

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Date: 08/19/1988	ISR Number: 541355-8	Report Type: Periodic		Company Report Numb	er: 880200	171001	Age:	28 YR	Gen	der: Female
Outcome	PT	Report Source	Product		Role	Manufacturer	D _o	ute	Dose/Unit	P 41
Other	Cardiovascular Disorder Nos Hyperventilation	Health Professional	Accutane		PS	Roche		AL	DOSCURI	Duration 57
Date: 08/19/1988	ISR Number: 542456-0	Report Type: Periodic	-	Company Report Numb	er: 870201	297001	Age:	35 YR	Gen	der: Female
Outcome	PT	Report Source	Product		Role	Manufastuum	ъ.	_4.	D #1.	
Other	Palpitations	Health Professional	Accutane		PS	Manufacturer Roche		ute :AL	Dose/Unit	Duration 9
Date: 08/19/1988	ISR Number: 542469-9	Report Type: Periodic		Company Report Numb	er: 870201	369001	Age:	23 YR	Gen	der: Male
Outcome	PT	Report Source	Product						-	- Iviaic
Other	Epistaxis	Health Professional	Accutane		Role	Manufacturer		ute	Dose/Unit	Duration
	Hypercholesterolaemia Hyperlipidaemia Nos Personality Disorder Nos		Acculance		PS	Roche	OR	AL		111
Date: 08/19/1988	ISR Number: 542481-X	Report Type: Periodic		Company Report Numb	er: 870200	738001	Age:	19 YR	Gen	der: Male
Outcome	Pr	Report Source	Product		Role	Manufacturer	D.	ute	Dose/Unit	Ps. 41
	Aspartate Aminotransferase Increased Depression Nec	Health Professional	Accutane		PS	Roche	OR		Dosevant	Duration 181
Date: 08/19/1988	ISR Number: 542579-6	Report Type: Periodic		Company Report Numb	er: 870201	316001	Age:	28 YR		der: Male
Outcome	PT	Report Source	Product					20 110	Vai	der: Male
Other	Abnormal Dreams	Health Professional			Role	Manufacturer	Ro	ule	Dose/Unit	Duration
	Impotence Libido Decreased	· ····································	Acoutane		PS	Roche	OR	AL		110
Date: 08/19/1988	ISR Number: 542580-2	Report Type: Periodic		Company Report Numb	er: 870201	327001	Age:	27 YR	Gen	der: Female
Outcome	PT	Report Source	Product		Role	Manufacturer			D 61 11	
Other	Emotional Disturbance Nos	Health Professional	Accutane		PS	Roche		ute	Dose/Unit	Duration
	Hostility Personality Disorder Nos		Intal		С	N. Octio	OR	AL		
Date: 09/09/1988	ISR Number: 542716-3	Report Type: Direct	,,	Company Report Numb	eg;		Age:	27 YR	Gen	der: Male
Outcome	PT	Report Source	Product		Role					
Disability	Alopecia	Consumer	Accutane		PS	Manufacturer Roche	Ro		Dose/Unit	Duration
	Depression Nec				to	Kocne	OR	AL		97
	Photosensitivity Reaction Nos Skin Disorder Nos									

Date: 08/19/1988	ISR Number: 544032-2	Report Type: Periodic		Company Report Numbe	er: 870201	223001	Age: 20 YR	Gene	ier: Female
Outcome	PT	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
Other	Atmesia Nec Arthralgia	Health Professional	Accutane		PS	Roche	ORAL		67
	Hyperlipidaemia Nos								
Date: 08/19/1988	ISR Number: 544040-1	Report Type: Periodic		Company Report Numbe	r: 870200	933001	Age: 17 YR	Gen	der: Male
Outcome	PT	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	
Other	Arnnesia Nec Arrhythmia Nos	Health Professional	Accutane		PS	Roche	ORAL	DOSE/OUR	Duration 120
	Chest Pain						Oldre		120
	Demutitis Exfoliative Nos								
Date: 08/19/1988	ISR Number: 544044-9	Report Type: Periodic		Company Report Numbe	r: 870200	0534001	Age: 19 YR	Gene	der: Female
Outcome	PT	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
Other	Asthenia Blood Bilimbin Increased	Health Professional	Accutane		PS	Roche	ORAL	17050 (////	31
	Depression Nec						344		31
<u>-</u>	Hepatitis Nos								
Date: 08/19/1988	ISR Number: 544088-7	Report Type: Periodic		Company Report Numbe	ar: 880200	046001	Age: 54 YR	Gent	ler: Male
Outcome	PT	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration .
Other	Personality Disorder Nos	Health Professional	Accutane		PS	Roche	ORAL	1505 CAR	DIMARION
Date: 08/19/1988	ISR Number: 544093-0	Report Type: Periodic		Company Report Numbe	r: 880200	0042001	Age: 22 YR		 der: Male
Outcome	<u>P</u> T	Report Source	Product	_			=		
Other	Chest Pain	Health Professional	Accutane		Role PS	Manufacturer Roche	Route	Dose/Unit	Duration
	Palpitations					Roche	ORAL		8
Date: 08/19/1988	ISR Number: 544096-6	Report Type: Periodic		Company Report Numbe	r: 870201	562001	Age: 14 YR	Gene	der: Female
Outcome	PT Dry Mouth	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
Other	Personality Disorder Nos	Health Professional	Accutane		PS	Roche	ORAL		21
			Tetracycline		С				
Date: 08/19/1988	ISR Number: 544121-2	Report Type: Periodic		Company Report Number	r: 880200	394001	Age:	Gene	ler: Unknown
Outcome	_ <u>PT</u>	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
Other	Hostility	Health Professional	Accutance		PS	Roche	ORAL		Datadon

Date: 11/02/1988	ISR Number: 553830-0	Report Type: Direct		Company Report Numb	ber:		Age: 16 YR	Ger	ıder: Male
Outcome	PT	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Hostility	Health Professional	Accutane		PS	Roche	ORAL	DOSECTION	
nada or Froinged	Mania Psychotic Disorder Nos		Tetracycline	,	C	110400	OKAL		14
	To you do to Disorded 140s		Retin-A		С				
Date: 10/28/1988	ISR Number: 554169-X	Report Type: Expedited	(15-Day)	Company Report Numi	ber: 880201	176001	Age: 16 YR	Ge	ıder: Male
Outcome	PT	Report Source	Product		D.1.	M	- -		
Hospitalization -	Bipolar I Disorder	Health Professional	Accutane		Role PS	Manufacturer Roche	Route	Dose/Unit	Duration
Initial or Prolonged Other	Condition Aggravated Hostility					Rocae	ORAL		22
	Psychotic Disorder Nos								
Date: 12/02/1988	ISR Number: 558399-2	Report Type: Expedited	(15-Day)	Company Report Numi	ber: 870103	027001	Age: 18 YR	Ger	nder: Male
Outcome	PT	Report Source	Product		Role	Manufacturer	- n		
Hospitalization -	Major Depressive Disorder Nos	Foreign	Accutane		PS PS	Roche	Route	Dose/Unit	Duration
Initial or Prolonged	Non-Accidental Overdose Paraesthesia Nec	Health Professional	Oxazepam		C	Roche	ORAL		1
	Speech Disorder Nec		Дохеріп Ну	drochloride	C				
	•		Methylpredi	nisolone	C				
			Erythromyc	in	С				,
Date: 12/19/1988	ISR Number: 559371-9	Report Type: Expedited ((15-Day)	Company Report Numb	жет: 880201	083001	Age: 18 YR	Ger	ider: Male
Outcome	<u>PT</u>	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Arthralgia Major Depressive Disorder Nos	Health Professional	Accutane		PS	Roche	ORAL	200001	14
Other	Psychotic Disorder Nos		Retin-A		SS	Ortho	0.0.2		14
Date: 01/19/1989	ISR Number: 565743-9	Report Type: Direct		Company Report Numi	oer:		Age: 17 YR	Ger	ıder: Female
Outcome	PT	Report Source	Product		Role	Manufacturer	Route		
Disability	Confusion	Health Professional	Accutane		PS	Roche	Koute	Dose/Unit	Duration
	Dry Mouth Dry Skin				15	косце			65
	Thinking Abnormal Nec								
Date: 02/22/1989	ISR Number: 569194-2	Report Type: Expedited (15-Day)	Company Report Numb	er: 890200	109001	Age: 43 YR	Ger	ıder: Male
Outcome	_ PT	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
Death	Delirium	Health Professional	Accutane		PS	Roche	ORAL	_ooo call	32
Hospitalization -							OIGH.		34

		TEDA.							
				e Escat Report		SOM (CONTROL			
			3 (1) (1) (1)	Of Information		Report			
Date: 02/22/1989	ISD N 1 . SCOLOL D								
	ISR Number: 569194-2	Report Type: Expedited	(15-Broduct	Company Report Numb	er: H60 200	109Minufacturer	Route	Dose/Unit	Duration
Outcome	PT	-	Accutane		PS	Roche	ORAL		32
Other	Delirium			•					
Date: 03/30/1989	ISR Number: 579176-2								
		Report Type: Expedited	(15-Day)	Company Report Numb	er: 890200	0199001	Age: 33 YR	Gen	ider: Male
Outcome Disability	PT Dysarthria	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	D
Disability	Hepatic Function Abnormal Nos	Health Professional	Accutane		PS	Roche	ORAL	DOSG CHIL	Duration
	Multiple Sclerosis						OKAL		731
	Vision Abnormal Nec	_							
Date: 03/30/1989	ISR Number: 579177-4	Report Type: Expedited (15-Day)		C		· · · · · · · · · · · · · · · · · · ·			
Outcome	PT			Company Report Numb	er: 880400212001		Age: 36 YR	Gen	ler: Female
Other	Amblyopia Nos	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Ataxia Nec	Foreign	Rosccutane		PS	Roche	ORAL		55
	Dysarthria	Health Professional	Ethinyl Esta		С				
2.4 02.70.40			Cyproterone	Acetate	С				
Date: 03/30/1989	ISR Number: 579183-X	Report Type: Expedited (15-Day)	Company Report Number	Company Report Number: 89U200209001				der: Male
Outcome	PT	Report Source	Product				Age: 19 YR	Gen	ider: Male
Hospitalization -	Delusion Nos	Health Professional	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
Initial or Prolonged Disability	Hallucination Nos		riccitane		PS	Roche	ORAL		132
Other	Major Depressive Disorder Nos Psychotic Disorder Nos								
									
Date: 05/12/1989	ISR Number: 583883-5	Report Type: Expedited (15-Day)	Company Report Number	er: 890200	393001	Age: 24 YR		d) e i
Outcome	PT	Report Source	Product					Gen	der: Male
Hospitalization -	Convulsions Nos	Health Professional	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
Initial or Prolonged Disability	Delirium		Accorate		PS	Roche	ORAL		
,	Encephalitis Nos Paralysis Nos								· .
Date: 06/28/1989	ISR Number: 596087-7								
	132 14 14 14 15 15 15 15 15 15 15 15 15 15 15 15 15	Report Type: Expedited (15-Day)	Company Report Number	r: 890200	522002	Age:	Gen	der: Unknown
Outcome	PT	Report Source	Product		Role	Manufacturer	-		
Hospitalization - initial or Prolonged	Schizophrenia Nos	Health Professional	Accutane		PS	Roche	Route	Dose/Unit	Duration .
or 1 toloniged					10	Roche	ORAL		
						•	•		
08/03/2000									

l	ISR Number: 599182-1	Report Type: Expedited (15-Day)		Company Report Number: 890200522001			Age: 17 YR	Gen	dow MA
Outcome	<u>PT</u>	Report Source	Product	· ·					
Hospitalization - Initial or Prolonged Other	Hypercholesterolaemia Hyperlipidaemia Nos Schizophrenia Nos	Health Professional	Accutane		PS	Manufacturer Roche	Route ORAL	Dose/Unit	Duration 121
Date: 08/08/1989	ISR Number: 601690-1	Report Type: Expedited (15-Day)		Company Report Number: 890200654001			Age: 18 YR		
Outcome Hospitalization -	PT Amnesia Nec	Report Source	Product		Role	Manufacturer	Route	Gen Dose/Unit	der: Male Duration
Initial or Prolonged	Blood Magnesium Decreased	Health Professional	Accutane		PS	Roche	ORAL	<u>Done cint</u>	140
Other	Hypocalcaernia Renal Tubular Disorder Nos								
Date: 08/25/1989	ISR Number: 608203-9	Report Type: Expedited (15-Day)		Company Report Number: 8900200658001		Age: 18 YR	Gender: Male		
Outcome Disability	PT Amblyopia Nos	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
Бізавініў	Depression Nec Skin Disorder Nos	Health Professional	Accutane		PS ·	Roche	ORAL		154
	Weight Decreased	·							
Date: 09/01/1989	ISR Number: 609517-9	Report Type: Expedited (15-Day)		Company Report Number: 890200754001			Age: 20 YR	Gen	ler: Male
Outcome	PT Alopecia	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Alopecia Condition Aggravated Psychotic Disorder Nos	Health Professional	Accutane Navane		PS C	Roche	ORAL	IASC CILL	29
Date: 10/05/1989	ISR Number: 618712-4	Report Type: Direct		Company Report Numbe			Age: 34 YR	Gen	
Outcome	PT	Report Source	Product		ъ.		. =		
	Agitation Confusion	Health Professional	Accutane		Role PS	Manufacturer Roche	Route ORAL	Dose/Unit	Duration 14
	Hallucination Nos								
	ISR Number: 623566-6	Report Type: Expedited (1		Company Report Number	r: 890200	886001	Age: 22 YR	Gene	ler: Female
Outcome	ISR Number: 623566-6	Report Source	5-Day)	Company Report Number	r: 890200 Role	886001 Manufacturer	Age: 22 YR	Gene Dose/Unit	
Outcome Hospitalization -	ISR Number: 623566-6		Product Accutane	Company Report Number	Role PS		•		Duration 21
Outcome Hospitalization -	ISR Number: 623566-6 PT Bipolar I Disorder	Report Source	Product Accutane Navane	Company Report Number	Role PS C	Manufacturer	Route		Duration
Date: 10/12/1989 Outcome Hospitalization - Initial or Prolonged	ISR Number: 623566-6 PT Bipolar I Disorder	Report Source	Product Accutane Navane Tegretol	Company Report Number	Role PS C C	Manufacturer	Route		Duration
Outcome Hospitalization -	ISR Number: 623566-6 PT Bipolar I Disorder	Report Source	Product Accutane Navane	Company Report Number	Role PS C	Manufacturer	Route		Duration