			Preeding	e Event Repar Of Informatio		Report			
Date: 05/13/1997 Outcome	ISR Number: 1924270-4	Report Type: Expedited		Company Report Num			Age: 21 YR	Ge	nder: Female
Other	Depression Nec	Report Source	Product		Role	Manufacturer			
ould	Haemoptysis	Consumer	Accutane		PS	Roche	Route	Dose/Unit	Duration
	Sinusitis Nos				13	Roche	ORAL		
Date: 04/28/1997	ISR Number: 1928328-5	Denord Trans. E. P.							
Outcome	PT	Report Type: Expedited	(15-Day)	Company Report Num	ber: 80117		Age: 15 YR	Ge	nder: Male
Hospitalization -	Amnesia Nec	Report Source	Product	_	Role	Manufacturer	Route		
Initial or Prolonged	Delusion Nos	Health Professional	Accutane		PS	Roche		Dose/Unit	Duration
	Hallucination Nos					Roche	ORAL	80	1
	Speech Disorder Nec								
Date: 06/09/1997	ISR Number: 1930045-2	D							
Outcome	-	Report Type: Expedited	(15-Day)	Company Report Numb	ber: 81719		Age: 16 YR	Cm	nder: Female
	PT Antari	Report Source	Product		Dala	34	-		remaie
Hospitalization - Initial or Prolonged	Aphasia Facial Palsy	Foreign	Roaccutane		Role	Manufacturer	Route	Dose/Unit	Duration
	Haemorrhagic Stroke	Health Professional	Cilest		PS	•	ORAL	1	91
	Hemiplegia				SS		ORAL		39
Date: 06/10/1997	ISR Number: 1932182-5								
0.4		Report Type: Expedited	(15-Day)	Company Report Numb	er: 76795		Age: 15 YR		ıder: Female
Outcome	PT	Report Source	Product		_		13 IX	Ger	ider: Female
Hospitalization - Initial or Prolonged	Disorder Neonatal Nos	Health Professional	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
or 1 statelinger	Hyperventilation Otitis Media Nos		riconanc		PS	Roche	ORAL		170
	Pneumonia Nos								
ate: 06/18/1997									
	ISR Number: 1932702-0	Report Type: Expedited (15-Day)	Company Report Numb	er: 82370		Aga, 10 ***		
Outcome	PT	Report Source	Product	- , ,			Age: 18 YR	Gen	der: Female
lospitalization -	Depression Nec	Health Professional			Role	Manufacturer	Route	Dose/Unit	Duration
nitial or Prolonged	Suicide Attempt		Accutane		PS	Roche	ORAL		1
ate: 05/23/1997	ISR Number: 1940398-7	Report Type: Expedited (15 Day)						-
Outcome	PT		io-Day)	Company Report Number	er: 81258		Age: 21 YR	Gen	der: Male
Other	Paranoia	Report Source	Product		Role	Manufacturer	Route		
	Psychotic Disorder Nos	Foreign	Roaccutane		PS			Dose/Unit	Duration
ite: 06/24/1997				<u> </u>			ORAL		62
	ISR Number: 1941955-4	Report Type: Expedited (1	5-Day)	Company Report Numbe	er: 82537		A 40.7		
utcome	<u>Pr</u>	Report Source	Danish	Forsymithe			Age: 18 YR	Gen	der: Male
ospitalization	Condition Aggravated	Foreign	Product		Role	Manufacturer	Route	Dose/Unit	Duration
itial or Prolonged	Psychotic Disorder Nos	v Orcigit	Roaccutane		PS	Roche			

FDA - Adverse Escat Reporting System (AERS Preedom Of Information (FCII) Report Date: 06/11/1997 ISR Number: 1948993-6 Report Type: Periodic Company Report Number: 74771 Age: 17 YR Gender: Female Report Source Product Depression Nec Role Manufacturer Dose/Unit Duration Accutane Dry Skin PS Roche ORAL Insomnia Nec Date: 06/11/1997 ISR Number: 1949100-6 Report Type: Periodic Company Report Number: 74270 Age: 35 YR Gender: Female Outcome Report Source Product Depression Nec Role Manufacturer Dose/Unit Duration Route Consumer Accutane Dermatitis Nos PS Roche ORAL Urticaria Nos Vasodilatation Date: 06/11/1997 ISR Number: 1949120-1 Report Type: Periodic Company Report Number: 73983 Age: 54 YR Gender: Male Outcome Report Source Product Other Role Impotence Dose/Unit Duration Health Professional Accutance PS ORAL 122 Date: 06/11/1997 ISR Number: 1949141-9 Report Type: Periodic Company Report Number: 75051 Age: 24 YR Gender: Female Report Source Product Emotional Disturbance Nos Role Manufacturer Route Dose/Unit Duration Consumer Libido Decreased Accutane PS Roche ORAL 40 Vaginitis Date: 06/11/1997 ISR Number: 1949149-3 Report Type: Periodic Company Report Number: 74930 Age: 20 YR Gender: Male Outcome Report Source Product Emotional Disturbance Nos Role Manufacturer Route Dose/Unit Duration Consumer Accutane Roche ORAL 92 Date: 06/11/1997 ISR Number: 1949481-3 Report Type: Periodic Company Report Number: 74926 Age: 20 YR Gender: Female Outcome Report Source Product Amnesia Nec Role Manufacturer Dose/Unit Duration Route Consumer Accutane PS Roche ORAL 80 154 Date: 06/11/1997 ISR Number: 1949510-7 Report Type: Periodic Company Report Number: 74873 Age: 48 YR Gender: Female Outcome Report Source Role Other Depression Nec Manufacturer Route Dose/Unit Duration Health Professional Pain Nos PS ORAL Pruritus Urticaria Nos

ISR Number: 1949679-4	Report Type: Periodic		Company Report Numbe	ar: 75238		Age: 37 YR	Gender: Female
PT Anxiety Nec Diarrhoea Nos Dry Skin Dyspnoea Nos	Report Source Health Professional	Product Accutane		Role PS	Manufacturer Roche	Route ORAL	Dose/Unit Duration 60 36
SR Number: 1949700-3	Report Type: Periodic		Company Report Number	r: 75163		Age:	Gender: Male
Asthenia Depression Nec Headache Nos Sedation	Report Source Consumer	Product Accutane		Role PS	Manufacturer Roche	Route	Dose/Unit Duration 120 141
SR Number: 1951133-0 PT	Report Type: Periodic	D. J. J	Company Report Number	r: 68118		Age: 49 YR	Gender: Female

Outcome	PT	Report Source	D 31					GE	mer: Male
Other	Asthenia	Consumer	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Depression Nec	Consume	Accutane		PS	Roche	ORAL	120	141
	Headache Nos							120	141
	Sedation								
Date: 06/11/1997	ISR Number: 1951133-0	Report Type: Periodic		Company Report Nun	nber: 68118		Age: 49 YR	Gen	der: Female
Outcome	PT	Report Source	Product				-		uci. Pemaie
	Dermatitis Nos	Consumer			Role	Manufacturer	Route	Dose/Unit	Duration
	Insomnia Nec		Accutane		PS	Roche	ORAL	40	6
	Pain Nos								·
Date: 06/11/1997	2014 (Mainter: 1933967-3	Report Type: Periodic		Company Report Num	nber: 76887		Age: 23 YR	Gen	der: Female
Outcome	PT	Report Source	Product					C) Gall	uer: Pemale
Other	Depression Nec	Consumer			Role	Manufacturer	Route	Dose/Unit	Duration
	Dry Eye Nec	Consulted	Accutane		PS	Roche	ORAL	40	27
	Nervousness								
Date: 06/11/1997	ISR Number: 1955990-3	Report Type: Periodic		Company Report Num	ıber: 76871		Age: 15 YR	Gen	der: Male
Outcome	PT	Report Source	Product			4.24			ner: mare
Other	Alopecia	Health Professional			Role	Manufacturer	Route	Dose/Unit	Duration
	Depression Nec	**************************************	Accutane		PS	Roche	ORAL	40	92
	Thinking Abnormal Nec								
Date: 06/11/1997	ISR Number: 1956054-5	Report Type: Periodic		Company Report Num	ber: 76785		Age: 37 YR	Gene	der: Female
Outcome	PT	Report Source	Product					· Gun	ser: Female
Other	Dyspareunia Nec	Health Professional			Role	Manufacturer	Route	Dose/Unit	Duration
	Vaginitis	Freezen F LOT COSTONAL	Accutane		PS	Roche	ORAL	60	
Date: 06/11/1997	ISR Number: 1956154-X	Report Type: Periodic		Company Report Numi	ber: 77341		Age: 20 YR	Geno	
Outcome	PT	Report Source	Product	-			74ger 20 11c	Gen	der: Female
Other	Anxiety Nec	Consumer			Role	Manufacturer	Route	Dose/Unit	Duration
	Dizziness (Exc Vertigo)	CONSUMER	Accutane		PS	Roche	ORAL	70	

08/03/2000

Date: 06/11/1997

Date: 06/11/1997

Other

FDA - Adverse Event Reporting System (ACRS) Freedom Of Information (FGI) Report

	ISR Number: 1958869-6	Report Type: Periodic		Company Report Num	ber: 77830		Age: 26 YR		
Outcomte	PT	Report Source	Product				11gc. 20 1 K	G	ender: Female
Other	Depression Nec	Consumer	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
	Drug Ineffective	····	Accutane		PS	Roche	ORAL	40	
	Emotional Disturbance Nos							,,,	
	Muscle Cramps								
Date: 06/11/1997	ISR Number: 1958889-1	Report Type: Periodic		Community			· <u> </u>		
Outcome	PT			Company Report Numb	er: 78355		Age: 23 YR	Ge	nder: Female
Other	Amblyopia Nos	Report Source	Product		Role	Manufacturer	Route		_
	Dermatitis Nos	Consumer	Accutane		PS			Dose/Unit	Duration
	Dry Skin	*	Ceftin			Roche	ORAL	80	
	Emotional Disturbance Nos				C				
Date: 06/11/1000									
Date: 06/11/1997	ISR Number: 1959132-X	Report Type: Periodic		Company Report Numb	77025				
Outcome	PT	Domand S		hand vebout MIMB	er: //y/5		Age: 31 YR	Ge	nder: Female
Other	Depression Nec	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	D#
		Health Professional	Accutane		PS :	Roche			Duration
Date: 06/11/1997	ISR Number: 1959139-2	D					ORAL.	80	69
		Report Type: Periodic		Company Report Numb	er: 77958		Age:		
Outcome	PT	Report Source	Product				Age.	Ge	nder: Unknown
Other	Depression Nec	Health Professional			Role	Manufacturer	Route	Dose/Unit	Duration
		Treaten i Totessional	Accutane		PS	Roche	ORAL		
Date: 06/11/1997	ISR Number: 1959175-6	Report Type: Periodic							
Outcome		resport Type. Terrounc		Company Report Number	er: 77777		Age: 16 YR	Ge	nder: Female
	PT	Report Source	Product					- Va	tuer: remale
Other	Emotional Disturbance Nos	Health Professional	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
	Headache Nos		riccutatie		PS	Roche	ORAL	60	
Date: 06/11/1997	ISR Number: 1959178-1	Report Type: Periodic							
Outcome	TOWN			Company Report Number	r: 77776		Age: 34 YR	Gen	ıder: Female
	PT	Report Source	Product		D-1-				remaie
Other	Amnesia Nec	Health Professional	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
		· · · · · · · · · · · · · · · · · · ·	- recurring		PS	Roche	ORAL	100	159
ete: 06/11/1997	ISR Number: 1959270-1	Report Type: Periodic		Comment Day 137					
Outcome	PT			Company Report Numbe	r: 77469		Age: 17 YR	Gen	der: Male
Other	Alopecia	Report Source	Product		Role	Manufacturer	D4-		
	Depression Nec	Consumer	Accutane		PS		Route	Dose/Unit	Duration
	Myalgia		Beconase			Roche	ORAL	60	66
	Personality Disorder Nos				С				

FDA - Adverse Event Reporting System (AERS) Freedom () Information (FDT) Report

Date: 06/11/1997	ISR Number: 1959280-4	Report Type: Periodic		Company Report Numbe	r: 77461		Age: 39 YR		_
Outcome	PT	Report Source	Product	•			Age: 39 IR	Ger	ider: Female
Other	Asthenia	Consumer	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
	Palpitations				PS	Roche	ORAL	40	
D.4. 06#4#000			Xanax		С				
Date: 06/11/1997	ISR Number: 1959459-1	Report Type: Periodic		Company Report Number	: 63526		Age: 16 YR	Ger	ıder: Female
Outcome	PT	Report Source	Product					ou.	idei. Pemaje
Other	Palpitations	Health Professional	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
	Ventricular Extrasystoles		Acculage		PS	Roche	ORAL		
Date: 06/11/1997	ISR Number: 1959645-0	Report Type: Periodic		Company Report Number	: 68575		Age: 28 YR		
Outcome	PT	Report Source	Product				Age. 20 I K	Gen	der: Female
Other	Drug Interaction Nos	Consumer			Role	Manufacturer	Route	Dose/Unit	Duration
	Major Depressive Disorder Nos	insuring	Accutane		PS	Roche	ORAL	20	60
			Paxil		C				Ģ0
			Synthroid		C				
Date: 06/11/1997	ISR Number: 1959658-9	Report Type: Periodic		Company Report Number	: 64803		Age: 17 YR	Gen	der: Malc
Outcome	PT	Report Source	Product		Role	36			Male
Other	Hostility	Health Professional	Accutane		PS	Manufacturer	Route	Dose/Unit	Duration
	Personality Disorder Nos				го	Roche	ORAL	80	153
Pate: 06/11/1997	ISR Number: 1959664-4	Report Type: Periodic		Company Report Number	64762				
Outcome	PT	D	_	y y suport ruminer	04702		Age: 35 YR	Gen	der: Female
Other	Confusion	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Emotional Disturbance Nos	Consumer	Accutane		PS	Roche	ORAL		
Date: 06/11/1997	ISR Number: 1959749-2						OKAL	80	32
	13ж (чиния: 1939/49-2	Report Type: Periodic		Company Report Number	64667		Age: 16 YR		
Outcome	PT	Report Source	Product				age. 10 IK	Gen	der: Female
Other	Asthenia	Consumer			Role	Manufacturer	Route	Dose/Unit	Duration
	Emotional Disturbance Nos	- California	Accutane		PS	Roche	ORAL	40	86
	Mucous Membrane Disorder Nos								
-1- 06/11/10s=									
ate: 06/11/1997	ISR Number: 1959790-X	Report Type: Periodic		Company Report Number:	64541				
Outcome	PT	Report Source	_	· · · · · · · · · · · · · · · · · · ·			Age: 28 YR	Geno	ler: Female
Other	Cyst Nos		Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Insomnia Nec	Health Professional	Accutane		PS	Roche	ORAL	80	Tour amost
	Pain Nos						CACAL	au	

FDA - Adverse Event Reporting System (AERS) Freedom Of Information (801) Report Date: 06/11/1997 ISR Number: 1960003-3 Report Type: Periodic Company Report Number: 66743 Age: 34 YR Gender: Female Outcome Report Source Product Role Hallucination Nos Manufacturer Route Dose/Unit Duration Health Professional Accutane PS Roche ORAL 212 Date: 06/11/1997 ISR Number: 1960006-9 Report Type: Periodic Company Report Number: 66735 Age: 41 YR Gender: Female Outcome PT Report Source Product Other Palpitations Role Manufacturer Route Dose/Unit Duration Health Professional Accutane PS Roche ORAL Acyclovir С Date: 06/11/1997 ISR Number: 1960012-4 Report Type: Periodic Company Report Number: 66676 Age: 27 YR Gender: Female Outcome Report Source Other Role Anorexia Manufacturer Health Professional Route Dose/Unit Duration Accutane Depression Nec PS Roche ORAL 75 Stupor Date: 06/11/1997 ISR Number: 1960017-3 Report Type: Periodic Company Report Number: 66674 Age: 34 YR Outcome Gender: Female Report Source Product Other Confusion Role Manufacturer Route Dose/Unit Duration Consumer Accutane Face Oedema PS Roche ORAL. Hallucination Nos Mucous Membrane Disorder Date: 06/11/1997 ISR Number: 1960027-6 Report Type: Periodic Company Report Number: 66639 Age: 23 YR Gender: Male Outcome Report Source Product Amblyopia Nos Dose/Unit Duration Health Professional Confusion PS Roche ORAL. Dizziness (Exc Vertigo) Paraesthesia Nec Date: 06/11/1997 ISR Number: 1960056-2 Report Type: Periodic Company Report Number: 67016 Age: 27 YR

Role

PS

C

C

Manufacturer

Roche

Route

ORAL

Report Source

Consumer

Product

Accutane

Prozac

Ativan

Depression Nec

Outcome

Other

Gender: Male

72

Dose/Unit Duration

				Ol Information		Report			
Date: 06/11/1997	ISR Number: 1960059-8	Report Type: Periodic		Company Report Numl	ber: 67010		Age: 40 YR	Ge	nder: Female
Outcome	PT	Report Source	Product		Role	Manufacturer		_	
Other	Bone Pain	Consumer	Accutane		PS	Roche	Route	Dose/Unit	Duration
	Depression Nec Myalgia				15	Rocale	ORAL	120	92
	Viral Infection Nos								
Date: 06/11/1997	ISR Number: 1960174-9	Report Type: Periodic		Company Report Numi	her: 67752	- <u> </u>			
Outcome	PT	Report Source		Tary and a second	Jen 07752		Age: 17 YR	Ger	nder: Female
Other	Dysphonia	Health Professional	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Hypercholesterolaemia	ricadul Professional	Accutane		PS	Roche	ORAL	40	99
Date: 06/11/1997	ISR Number: 1960185-3	Report Type: Periodic		Company Report Numb	er: 67733		Age:		nder: Male
Outcome	PT	Report Source	Product		ъ.		-	Ga	nder: Male
Other	Hormone Level Nos Abnormal	Health Professional	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
	Palpitations		Acculance		PS	Roche	ORAL	60	89
	Tachycardia Nos Thyroiditis Nos								
Date: 06/11/1997	ISR Number: 1960583-8	D 45 D 4 T							
		Report Type: Periodic		Company Report Numb	er: 77280		Age: 32 YR	Gen	ıder: Female
Outcome	PT	Report Source	Product		Role	Manufacturer		_	
Other	Palpitations	Health Professional	Accutane		PS	Roche	Route	Dose/Unit	Duration
			Vicodin		c	Roche	ORAL	40	30
			Aspirin		c				
Date: 06/11/1997	ISR Number: 1960778-3	Report Type: Periodic	•						
Outcome				Company Report Numb	er: 68355		Age: 23 YR	Gen	ıder: Female
Other	PT Depression Nec	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
Outer	tychicsztost IASC	Health Professional	Accutane		PS	Roche	ORAL	40	TALENTON
Date: 06/11/1997	ISR Number: 1961064-8	Report Type: Periodic		Company Report Numb	er: 70220		Age: 20 YR		der; Male
Outcome	PT	Report Source	Product		D-1-		=		der: Male
Other	Depression Nec	Consumer	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
	Emotional Disturbance Nos		Accurage		PS	Roche	ORAL	80	
Date: 06/11/1997	ISR Number: 1961071-5	Report Type: Periodic		Company Report Numb	er: 70218		Age: 23 YR	Gen	der: Female
Outcome	PT	Report Source	Product		Dala	Manuel			
Other	Depression Nec	Consumer	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
	Insomnia Nec				PS	Roche	ORAL	40	53
	Thinking Abnormal Nec								

FDA - Adverse Event Reporting System (ATRS) Freedom Of Information (FOI) Report Date: 06/11/1997 ISR Number: 1961083-1 Report Type: Periodic Company Report Number: 69930 Age: 16 YR Gender: Female Report Source Product Role Manufacturer Route Dose/Unit Duration Depression Nec Health Professional Accutane PS Roche ORAL 60 23 Date: 06/11/1997 ISR Number: 1961133-2 Report Type: Periodic Company Report Number: 70328 Age: 19 YR Gender: Female Outcome PT Report Source Product Role Manufacturer Route Dose/Unit Duration Alopecia Other Consumer Accutane PS Roche ORAL 139 Depression Nec Epistaxis Myalgia Date: 06/11/1997 ISR Number: 1961154-X Report Type: Periodic Company Report Number: 76301 Age: 18 YR Gender: Female Outcome Report Source Product Role Dose/Unit Duration Anxiety Nec Health Professional Accutane PS ORAL 60 Hyperkinetic Syndrome 17 Nervousness Date: 06/11/1997 ISR Number: 1961261-1 Report Type: Periodic Company Report Number: 72915 Age: 17 YR Gender: Male Outcome PT Report Source Product Role Route Dose/Unit Duration Asthenia Consumer Accutane PS Roche ORAL 80 Depression Nec Dizziness (Exc Vertigo) Hypercholesterolaemia Date: 06/11/1997 ISR Number: 1961675-X Report Type: Periodic Company Report Number: 63528 Age: 29 YR Gender: Female Outcome Report Source Product Role Route Dose/Unit Duration Other Depression Nec Health Professional Accutane PS Roche ORAL 157 Dry Skin Emotional Disturbance Nos Headache Nos Date: 06/11/1997 ISR Number: 1961708-0 Report Type: Periodic Company Report Number: 63458 Age: 18 YR Gender: Male Outcome Report Source Product Role Manufacturer Dose/Unit Duration Depression Nec Other Consumer Accutane PS ORAL Dermatitis Nos 80 Dry Skin Myalgia

FDA - Adverse Event Reporting System (AERS) Freedom Of Information (FOI) Report

Date: 06/11/1997	ISR Number: 1962002-4	Report Type: Periodic		Company Report Number: (52931		Asia Asia		
Outcome	PT	Report Source	Product				Age: 15 YR	Ge	nder: Male
Other	Depression Nec	Health Professional			ole	Manufacturer	Route	Dose/Unit	Duration
	Emotional Disturbance Nos	TAGALUT I TOTESSIONAL	Accutane	P	S	Roche	ORAL	100	
Date: 06/11/1997	ISR Number: 1962021-8	Report Type: Periodic		Company Report Number: 6	52374		Age: 14 YR		nder: Male
Outcome	PT	Report Source	Product	**				- Ga	nder: Male
Other	Emotional Disturbance Nos	Health Professional	Accutane	_	ole	Manufacturer	Route	Dose/Unit	Duration
	· · · · · · · · · · · · · · · · · · ·		· mountine	P	S	Roche	ORAL	80	158
Date: 06/11/1997	ISR Number: 1962755-5	Report Type: Periodic		Company Report Number: 6	2230		Arri 26 MD		-
Outcome	PT	Report Source	Product				Age: 36 YR	Ge	nder: Male
Other	Confusion	Health Professional			ole	Manufacturer	Route	Dose/Unit	Duration
	Vascular Disorder Nos		Accutane	P	8	Roche	ORAL	80	182
Date: 06/11/1997	ISR Number: 1962822-6	Report Type: Periodic		Company Report Number: 6	6401				
Outcome	PT	Report Source			0471		Age: 33 YR	Ger	nder: Female
Other	Dry Mouth	Health Professional	Product	R	ole	Manufacturer	Route	Dose/Unit	Duration
	Dysphonia	ricalui Professional	Accutane	PS	3	Roche	ORAL	120	134
			Aspirin	. С				120	134
			Naphazoline	C					
Date: 06/11/1997	ISR Number: 1963311-5	Report Type: Periodic		Company Report Number: 6	7940		A 2037D		
Outcome	_ PT	Report Source	Product				Age: 30 YR	Ger	nder: Female
Other	Arthralgia	Consumer			ole	Manufacturer	Route	Dose/Unit	Duration
	Asthenia	Consumer	Accutane	PS	:	Roche	ORAL	60	7
	Depression Nec								·
Date: 06/11/1997	ISR Number: 1963313-9	Report Type: Periodic		Company Report Number: 6	1000		~_ -		
Outcome	PT	Report Source	Product	I - J P T T C			Age: 40 YR	Gen	der: Female
Other	Asthenia	Health Professional		Re		Manufacturer	Route	Dose/Unit	Duration
	Diarrhoea Nos	Taxani I Tot Castolial	Accutane	PS	1	Roche	ORAL		123
	Dry Skin								
	Palpitations		·						
ate: 06/11/1997	ISR Number: 1963340-1	Report Type: Periodic		Company Report Number: 62	2441				
Outcome	PT	Report Source	Decident	VF			Age: 34 YR	Gen	der: Male
Other	Asthenia	Consumer	Product	Ro		Manufacturer	Route	Dose/Unit	Duration
	Depression Nec	COMMINA	Accutane	PS		Roche	ORAL		123
	Libido Decreased								123

FDA - Adverse Event Reporting System (AERS) Freedom Of Information (FOE Report

Date: 06/11/1997 ISR Num Outcome PT Emotic Other ISR Num ISR Num Outcome PT Emotic Other ISR Num ISR Num Outcome PT Person Outcome PT Anxiety Outcome PT Anxiety Outcome PT Anxiety Other Anxiety Myalging Pancest Weight	and Dreams aber: 1963533-3 onal Disturbance Nos Field Defect Nos ber: 1963547-3 onal Disturbance Nos ber: 1963703-4 ality Disorder Nos	Report Source Health Professional Report Type: Periodic Report Source Consumer Report Type: Periodic Report Source Health Professional Report Type: Periodic Report Source Health Professional	Product Accutane Nordette Product Accutane Claritin-D Vitamins Product Accutane	Company Report Num Company Report Num Company Report Num	Role PS C C C ther: 71280 Role PS	Manufacturer Roche Manufacturer Roche Manufacturer Roche	Age: 21 YR Route ORAL Age: 23 YR Route ORAL Age: 22 YR Route ORAL Age: 35 YR	Dose/Unit 40 Ge Dose/Unit 80 Ger Dose/Unit 80	nder: Female Duration 141 Duration 141 Duration 141
Date: 06/11/1997 ISR Num Outcome PT Emotic Other ISR Num ISR Num Outcome PT Emotic Other ISR Num ISR Num Outcome PT Person Outcome PT Anxiety Outcome PT Anxiety Outcome PT Anxiety Other Anxiety Myalging Pancest Weight	onal Disturbance Nos Field Defect Nos ther: 1963547-3 onal Disturbance Nos ther: 1963703-4	Health Professional Report Type: Periodic Report Source Consumer Report Type: Periodic Report Source Health Professional Report Type: Periodic Report Type: Periodic	Accutane Nordette Product Accutane Claritin-D Vitamins Product Accutane	Company Report Num	PS C Aber: 71221 Role PS C C C Aber: 71280 Role PS C C Aber: 71280	Manufacturer Roche Manufacturer	ORAL Age: 23 YR Route ORAL Age: 22 YR Route ORAL	Ge Dose/Unit 80 Ger Dose/Unit 80	nder: Female Duration 141 nder: Female Duration
Outcome PT Other Emotic Visual Visual Date: 06/11/1997 ISR Numl Other Emotic Date: 06/11/1997 ISR Numl Outcome PT Person ISR Numl Outcome PT Other Anxiety Myalgin Pracest Weight Weight	onal Disturbance Nos Field Defect Nos ber: 1963547-3 onal Disturbance Nos ber: 1963703-4	Report Type: Periodic Report Source Consumer Report Type: Periodic Report Source Health Professional Report Type: Periodic Report Type: Periodic	Product Accutane Claritin-D Vitamins Product Accutane	Company Report Num	C Role PS C C C ther: 71280 Role PS Solution: 76515	Manufacturer Roche Manufacturer	Age: 23 YR Route ORAL Age: 22 YR Route ORAL	Ger Dose/Unit 80 Ger Dose/Unit 80	Duration 141 nder: Female Duration
Outcome PT Other Emotic Visual Visual Date: 06/11/1997 ISR Numl Other Emotic Date: 06/11/1997 ISR Numl Outcome PT Person ISR Numl Outcome PT Other Anxiety Myalgin Pracest Weight Weight	onal Disturbance Nos Field Defect Nos ber: 1963547-3 onal Disturbance Nos ber: 1963703-4	Report Source Consumer Report Type: Periodic Report Source Health Professional Report Type: Periodic Report Source	Product Accutane Claritin-D Vitamins Product Accutane	Company Report Num	Role PS C C C C C Role PS Her: 71280 PS Role PS Role PS C C C Role PS Role PS Role PS Role PS C C C C C C C C C C C C C C C C C C	Roche Manufacturer	Route ORAL Age: 22 YR Route ORAL	Dose/Unit 80 Ger Dose/Unit 80	Duration 141 nder: Female Duration
Outcome PT Other Emotic Visual Visual Date: 06/11/1997 ISR Numl Other Emotic Date: 06/11/1997 ISR Numl Outcome PT Person ISR Numl Outcome PT Other Anxiety Myalgin Pracest Weight Weight	onal Disturbance Nos Field Defect Nos ber: 1963547-3 onal Disturbance Nos ber: 1963703-4	Report Source Consumer Report Type: Periodic Report Source Health Professional Report Type: Periodic Report Source	Accutane Claritin-D Vitamins Product Accutane	Company Report Num	Role PS C C C ther: 71280 Role PS	Roche Manufacturer	Route ORAL Age: 22 YR Route ORAL	Dose/Unit 80 Ger Dose/Unit 80	Duration 141 nder: Female Duration
Other Emotic Visual Date: 06/11/1997 ISR Numl Outcome PT Emotic Outcome PT Persons Date: 06/11/1997 ISR Numl Outcome PT Outcome PT Outcome PT Outcome PT Auxiety Myalgi Paraest Weight	Field Defect Nos ther: 1963547-3 onal Disturbance Nos her: 1963703-4	Consumer Report Type: Periodic Report Source Health Professional Report Type: Periodic Report Source	Accutane Claritin-D Vitamins Product Accutane	Company Report Num	Role PS C C C ther: 71280 Role PS	Roche Manufacturer	Route ORAL Age: 22 YR Route ORAL	Dose/Unit 80 Ger Dose/Unit 80	Duration 141 nder: Female Duration
Visual	Field Defect Nos ther: 1963547-3 onal Disturbance Nos her: 1963703-4	Consumer Report Type: Periodic Report Source Health Professional Report Type: Periodic Report Source	Accutane Claritin-D Vitamins Product Accutane		PS C C C Taber: 71280 Role PS Aber: 76515	Roche Manufacturer	ORAL Age: 22 YR Route ORAL	Gei Dose/Unit	141 nder: Female Duration
Date: 06/11/1997 ISR Numl Outcome PT Emotion Date: 06/11/1997 ISR Numl Outcome PT Persons Date: 06/11/1997 ISR Numl Outcome PT Anxiety Other Anxiety Myalgi Paraest Weight	onal Disturbance Nos ber: 1963703-4	Report Type: Periodic Report Source Health Professional Report Type: Periodic Report Source	Claritin-D Vitamins Product Accutane		C C Ther: 71280 Role PS	Manufacturer	Age: 22 YR Route ORAL	Ger Dose/Unit 80	nder: Female Duration
Outcome PT Other Emotio Date: 06/11/1997 ISR Numl Outcome PT Person ISR Numl Outcome PT Other Anxiety Myalgin Pracest Weight Weight	onal Disturbance Nos ber: 1963703-4	Report Source Health Professional Report Type: Periodic Report Source	Product Accutane Product		C ther: 71280 Role PS ther: 76515		Route ORAL	Dose/Unit 80	nder: Female Duration
Outcome PT Other Emotio Date: 06/11/1997 ISR Numl Outcome PT Person ISR Numl Outcome PT Other Anxiety Myalgin Pracest Weight Weight	onal Disturbance Nos ber: 1963703-4	Report Source Health Professional Report Type: Periodic Report Source	Product Accutane Product		Role PS ther: 76515		Route ORAL	Dose/Unit 80	Duration
Outcome PT Other Emotio Date: 06/11/1997 ISR Numl Outcome PT Person ISR Numl Outcome PT Other Anxiety Myalgin Pracest Weight Weight	onal Disturbance Nos ber: 1963703-4	Report Source Health Professional Report Type: Periodic Report Source	Accutane		Role PS		Route ORAL	Dose/Unit 80	Duration
Other Emotic Date: 06/11/1997 ISR Numl Outcome PT Persons Outcome PF Other Anxiety Myalgi Panest Weight	ber: 1963703-4	Health Professional Report Type: Periodic Report Source	Accutane		Role PS		Route ORAL	Dose/Unit 80	Duration
Other Emotic Date: 06/11/1997 ISR Numl Outcome PT Persons Outcome PF Other Anxiety Myalgi Panest Weight	ber: 1963703-4	Health Professional Report Type: Periodic Report Source	Accutane	Company Report Num	PS Der: 76515		ORAL.	80	
Date: 06/11/1997 ISR Numb Outcome PT Persons Date: 06/11/1997 ISR Numb Outcome PF Anxiety Other Anxiety Myalgi Paraest Weight	ber: 1963703-4	Report Type: Periodic	Product	Company Report Num	ber: 76515	Roche	ORAL.	80	
Outcome PT Person Date: 06/11/1997 ISR Numl Outcome PT Other Anxiety Myalgi Panest Weight		Report Source		Company Report Num		 			idam P. 1
Outcome PT Persons Date: 06/11/1997 ISR Numl Outcome PT Other Anxiety Myalgis Paraestl Weight		Report Source		Company Report Num			Age: 35 YR	Ger	idam E. 1
Persons Date: 06/11/1997 ISR Numl Outcome PT Anxiety Myalgi Panestl Weight	ality Disorder Nos								
Outcome PT Other Anxiety Myalgii Pancestl Weight	ality Disorder Nos	Health Professional			Role	Manufacturer			Tenate
Outcome PT Other Anxiety Myalgi Paraestl Weight			Accutane		PS PS	Roche	Route	Dose/Unit	Duration
Outcome PT Other Anxiety Myalgi Paraestl Weight						Roche	ORAL		76
Other Anxiety Myalgi Paraestl Weight	ber: 1963730-7	Report Type: Periodic		Company Report Num	her 72347				
Myalgi Paraestl Weight		Report Source	n				Age: 22 YR	Gen	ider: Female
Paraestl Weight	y Nec	Health Professional	Product		Role	Manufacturer	Route	Dose/Unit	Duration
Weight	ia	ricaim riolessional	Accutane		PS	Roche	ORAL	40	181
	hesia Nec							70	101
Date: 06/11/1997 ISR Numb	Decreased								
	ber: 1963748-4	Report Type: Periodic					 		<u> </u>
Outcome PT		- , -		Company Report Numb	ber: 73303		Age: 27 YR	Gen	der: Female
		Report Source	Product		Role	Manufacturer	D		
Other Palpitat	uons	Health Professional	Accutane		PS PS	Roche	Route	Dose/Unit	Duration
Date: 06/11/1997 ISB Numb				· · · · · · · · · · · · · · · · · · ·		- Kocile	ORAL	40	56
ISR Numb	ber: 1963802-7	Report Type: Periodic		Company Report Numb	ber: 73182				
Outcome PT		P	D 3 - 4				Age: 18 YR	Gen	der: Female
Other Depress			Product		Role	36. 4.			_
Weight	sion Nec	Report Source Health Professional	Accutane		Kole	Manufacturer	Route	Dose/Unit	Duration

FDA - Adverse Event Reporting System (AERS). Freedom Of Information (FOI) Report

Date: 06/11/1997	ISR Number: 1963962-8	Report Type: Periodic		Company Report Number: 72351		Age: 33 YR			_
Outcome	PT PT	Report Source	Product	Role	Manufacturer	Route		nder: Male	
Other	Depression Nec Hair Disorder Nos	Consumer	Accutance	PS	Roche		Dose/Unit	Duration	
	rian Disorder Nos		Valium	c	Rocile	ORAL	80	22	
			Ibuprofen	c					
Date: 06/11/1997	ISR Number: 1965194-6	Report Type: Periodic		Company Report Number: 70616		Age: 29 YR			
Outcome	PT	Report Source	Product			Age. 29 I K	Ge	nder: Female	
Other	Amenorrhoea Nos	Health Professional		Role	Manufacturer	Route	Dose/Unit	Duration	
	Dyspareunia Nec	Treatm Trotesaronni	Accutane	PS	Roche	ORAL	20	92	
· · · · · · · · · · · · · · · · · · ·	Mucous Membrane Disorder Nos								
Date: 06/11/1997	ISR Number: 1965408-2	Report Type: Periodic		Company Report Number: 72008		Age: 17 YR			_
Outcome	PT	Report Source	Dec de la			Age: 17 YR	Ger	ıder: Male	
Other	Anorexia	Consumer	Product	Role	Manufacturer	Route	Dose/Unit	Duration	
	Depression Nec	Consumer	Accutane	PS	Roche	ORAL		184	
	Emotional Disturbance Nos								
Date: 06/11/1997	ISR Number: 1965565-8	Report Type: Periodic		Company Report Number: 71278		Age: 39 YR		ider: Female	_
Outcome	PT	Report Source	Product				Gq	ider: Female	
Other	Anxiety Nec	Consumer	Accutane	Role	Manufacturer	Route	Dose/Unit	Duration	
	Depression Nec		riccutance	PS	Roche	ORAL	40	154	
	Influenza Like Illness								
	Rhinitis Nos								
Date: 06/11/1997	ISR Number: 1965622-6	Report Type: Periodic		Company Report Number: 66158		Age: 20 YR	·	der: Female	
Outcome	PT	Report Source	Product	.	122 2 3 6		Oth	uei: remaie	
Other .	Bacterial Infection Nos	Health Professional	Accutane	Role	Manufacturer	Route	Dose/Unit	Duration	
	Dyspareunia Nec		riccutante	PS	Roche	ORAL		124	
	Vaginitis				45.4				
Date: 06/11/1997	ISR Number: 1965629-9	Report Type: Periodic		Company Report Number: 66136	·	Age: 34 YR			
Outcome	PT	Report Source	Product			6 1K	Gen	der: Female	
Other	Depression Nec	Consumer		Role	Manufacturer	Route	Dose/Unit	Duration	
	Dizziness (Exc Vertigo)	monter	Accutane	PS	Roche	ORAL	20	178	
	Headache Nos								
	Myalgia								

	100	I	reedom	Event Reports If Information		Report			
Date: 06/11/1997	ISR Number: 1965741-4	Report Type: Periodic		Company Report Number	r: 73477		Age: 29 YR	Ge	nder: Female
Outcome	PT PT	Report Source	Product		Role	Manufacturer			- remite
Other	Amhlyopia Nos		Accutane		PS		Route	Dose/Unit	Duration
	Amenorrhoea Nos Depression Nec				гэ	Roche	ORAL	80	
	Dry Eye Nec								
Date: 06/11/1997	ISR Number: 1965743-8	Report Type: Periodic	·	Company Report Number	72476				
Outcome	PT			Company Report Number	: /34/6		Age: 32 YR	Ges	nder: Female
Other	Abnormal Dreams	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
-	Asthenia	Consumer	Accutane		PS	Roche	ORAL	20	
•	Emotional Disturbance Nos		Zoloft		С			20	21
	Skin Disorder Nos								
Date: 06/11/1997	ISR Number: 1965847-X	Report Type: Periodic		Company Report Number	: 75899		A		
Outcome	PT	Report Source	Dundand	- •	,		Age: 41 YR	Gen	ıder: Female
Other	Emotional Disturbance Nos	Health Professional	Product		Role	Manufacturer	Route	Dose/Unit	Duration
		- Totoground	Accutane		PS	Roche	ORAL	40	80
Date: 06/11/1997	ISR Number: 1965939-5	Report Type: Periodic		Company Report Number	75290		Age: 41 YR		
Outcome	PT	Report Source	Product	-			rige: 41 IK	Gen	ider: Male
Other	Emotional Disturbance Nos	Consumer	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
	Gastritis Nos		Erythromycin		PS	Roche	ORAL.	40	30
	Skin Disorder Nos		Valiom		С				
Date: 06/11/1997	ISR Number: 1965984-X	D	1 4110111		C				
0-4		Report Type: Periodic		Company Report Number	65917		Age: 34 YR	Gen	der: Female
Outcome Other	PT Alopecia	Report Source	Product		Role	Manufacturer	Route		
-Anter	Depression Nec	Consumer	Accutane		PS	Roche		Dose/Unit	Duration
	Dermatitis Nos		Paxil		c		ORAL	40	
	Ecchymosis								
Date: 06/11/1997	ISR Number: 1966213-3	Report Type: Periodic							
Outcome	PT			Company Report Number:	75904		Age: 37 YR	Gene	der: Female
Other	Depression Nec	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Drug Interaction Nos	Health Professional	Accutane		PS	Roche	ORAL	160	THE SHOIL
	Drug Level Nos Below		Depakote		SS	Abbott	ORAL	100	
	Therapeutic		Wellbutrin		С		OIGH		
			Cytomel		С				

Date: 06/11/1997	ISR Number: 1966230-3	Denost Town D. 1 #			***************************************			
Outcome	PT	Report Type: Periodic		Company Report Number	r: 75807		Age: 18 YR	Gender: Male
Other	Asthenia	Report Source	Product		Role	Manufacturer	Route	Dose/Unit Duration
	Thinking Abnormal Nec	Consumer	Accutane		PS	Roche	ORAL	80
Date: 06/11/1997	ISR Number: 1966614-3	Report Type: Periodic		Company Report Numbe	r: 75615	· · · · · · · · · · · · · · · · · · · 	Age: 17 YR	
Outcome	PT	Report Source	Product				. Age: 17 YR	Gender: Male
Other	Asthenia	Health Professional	Accutane		Role	Manufacturer	Route	Dose/Unit Duration
	Hyperlipidaemia Nos Nervousness	2 XXXXXXXIII	Ассиале		PS	Roche	ORAL	40 245
	Sinusitis Nos							*
Date: 06/11/1997	ISR Number: 1966615-5	Report Type: Periodic	·—	Company Report Numbe	r: 75611	-	Age: 15 YR	0.1
Outcome	PT	Report Source	Product				Age. 13 1R	Gender: Male
Other	Comeal Lesion Nos	Consumer	Accutane		Role	Manufacturer	Route	Dose/Unit Duration
<u>.</u>	Depression Nec Dry Eye Nec		recutant		PS	Roche	ORAL	60
Date: 06/11/1997	ISR Number: 1966616-7	Report Type: Periodic		Company Report Numbe	r: 75609		Age: 41 YR	Gender: Male
Outcome	PT	Report Source	Product					Gender: Male
Other	Palpitations	Consumer	Accutane		Role PS	Manufacturer	Route	Dose/Unit Duration
	Supraventricular Extrasystoles	<u> </u>			rs	Roche	ORAL	80 154
Date: 06/11/1997	ISR Number: 1966622-2	Report Type: Periodic		Company Report Number	75492		Age: 41 YR	Gender: Female
Outcome	PT	Report Source	Product		Role	Mountain		
Other	Libido Decreased	Health Professional	Accutane		PS	Manufacturer Roche	Route	Dose/Unit Duration
Date: 06/11/1997	ISR Number: 1967172-X	Report Type: Periodic				Rocne	ORAL	
Outcome	PT	*		Company Report Number	75960		Age: 40 YR	Gender: Female
	Menstrual Disorder Nos	Report Source Health Professional	Product		Role	Manufacturer	Route	Dose/Unit Duration
	Nervousness	ricaiui Professionai	Accutane		PS	Roche	ORAL	80
			Multivitamins	1	С			
			Synthroid		C			
			Propranolol		C			
			Fiorinal		C			
Oute: 11/13/1997	ISR Number: 3000460-7	Report Type: Expedited (15	-Day)	Company Report Number	: 80181		Age: 17 YR	Gender: Female
Outcome	Cardian Marrows No.	Report Source	Product		Role	Manufacturer	Route	
Congenital Anomaly	Cardiac Murmur Nos Complications Of Maternal	Health Professional	Accutane		PS		ORAL	Dose/Unit Duration

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Pate: 11/17/1997	ISR Number: 3000973-8	Report Type: Expedited (1	5-Day)	Company Report Numb	er: 89723		Age:	Ges	ıder: Female
Outcome	PT	Report Source	Product		Role	Manufacturer			
Congenital Anomaly	Complications Of Maternal Exposure To Therapuetic Drugs	Other	Accutane		PS	Manuacturer	Route	Dose/Unit	Duration
	Developmental Coordination				13		ORAL		
	Disorder Nos								
	Difficulty In Walking								
· · · · · · · · · · · · · · · · · · ·	Thinking Abnormal Nec								
Date: 12/01/1997	ISR Number: 3003385-6	Report Type: Expedited (1	5-Day)	Company Report Number	er: 89535		Age: 39 YR	Ger	ıder:
Outcome	_ PT	Report Source	Product		ъ.,				
Other	Confusion	Health Professional	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
	Herpes Simplex		····		PS		ORAL		
	Lymphadenopathy						ž.		
	Mumps Pyrexia								
	Sore Throat Nos								
	Swelling Nos								
	Weakness								
Date: 12/01/1997	ISR Number: 3003535-1								
Outcome	PT	Report Type: Expedited (1:	5-Day)	Company Report Number	r: 88810		Age: 17 YR	Gen	der: Male
Hospitalization -	Anorexia	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
Initial or Prolonged	Balance Impaired Nos	Foreign	Roaccutane		PS		ORAL	- DOG CARE	1741 441011
•	Cheilitis	Health Professional					OKAL		
	Confusion			*			A 10 10 10 10 10 10 10 10 10 10 10 10 10		
	Disturbance In Attention Nec								
	Dizziness (Exc Vertigo)								
	Fatigue								
	Headache Nos								
	Loss Of Consciousness Nec						*		
	Muscle Weakness								
	Syncope Visual Disturbance Nos								
10/01/105									
Pate: 12/01/1997	ISR Number: 3003537-5	Report Type: Expedited (15	i-Day)	Company Report Numbe	r; 90195	-	Age: 42 YR	Gene	der: Female
Outcome	PT	Report Source	Product		Role	Manufacture	-		remate
Other	Depression Nec		Accutane			Manufacturer	Route	Dose/Unit	Duration
	Suicidal Ideation		Klonopin		PS		ORAL		
			-		С				
			Trazodone		C				
			Benadryl		С				

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FDA - Adverses Event Reporting System (APRS) Freedom Of Information (FOI) Report

Date: 12/02/1997	ISR Number: 3003878-1	Report Type: Expedited	(15-Day)	Company Report Number: 90489		Age: 19 YR		nneas.
Outcome	PT	Report Source	Product					
Hospitalization - Initial or Prolonged	Depression Nec Hallucination Nos	Other	Accutane	Role PS	Manufacturer	ORAL	Dose/Unit Duration	-
Date: 12/08/1997	ISR Number: 3004624-8	Report Type: Expedited	(15-Day)	Company Report Number: 90973		Age: 30 YR	Gender: Female	—-
Outcome	<u>PT</u>	Report Source	Product			•	Gender: Female	,
Life-Threatening	Failure To Thrive		Accutane	Role	Manufacturer	Route	Dose/Unit Duration	_
Congenital Anomaly	Lipid Metabolism Disorder Nos Low Set Ears		Accusage	PS		ORAL		
	Mental Retardation Severity Unspecified							
Date: 12/08/1997	ISR Number: 3004636-4	Report Type: Expedited	(15-Day)	Company Report Number: 55633	 	Age: 28 YR	Gender: Female	<u></u>
Outcome	PT	Report Source	Product	Role	Manufacturer	D4-		
ife-Threatening	Depression Nec	Foreign	Roaccutane		Munimactur et	Route	Dose/Unit Duration	
Iospitalization - nitial or Prolonged	Suicide Attempt	Health Professional	Lexomil	SS		ORAL		
			Ludiomil	С				
			Maprotiline	c				
Pate: 12/10/1997	ISR Number: 3005621-9	Report Type: Expedited	(15-Day)	Company Report Number: 88658		Age: 16 YR	Gender: Female	
Outcome	<u>PT</u>	Report Source	Product		221.6	•	Gender. Female	•
Other	Dizziness (Exc Vertigo)	Foreign	Roaccutane	Role	Manufacturer	Route	Dose/Unit Duration	
	Headache Nos	Health Professional	Diane 35	13		ORAL.		
	Syncope Visual Disturbance Nos		Diane 33	C ·				
Pate: 12/23/1997					<u></u>			
,	ISR Number: 3010724-9	Report Type: Expedited	(15-Day)	Company Report Number: 91491		Age:	Gender:	_
Outcome	PT	Report Source	Product	n_1_	35 .		o manage.	
Other	Coma Nec	Health Professional	Accutane	Role PS	Manufacturer	Route	Dose/Unit Duration	
	Convulsions Nos		Dilantin			ORAL		
	Depression Nec		Duquun	SS		INTRAVEN		
						OUS DRIP		
	Dysarthria Hypotension Short-Term Memory Loss Status Epilepticus Suicide Attempt					OUS DRIP		

FDA - Adverse Event Reporting System (AERS) . Freedom Of Information (FOI) Report

Date: 12/31/1997	ISR Number: 3013336-6	Report Type: Expedited	(15-Day)	Company Report Numbe	r: 90404		Age: 19 YR	Gender: Male
Outcome	PT	Report Source	Product					Gender: Male
Hospitalization -	Depression Nec	Health Professional	Accutane		Role	Manufacturer	Route	Dose/Unit Duration
Initial or Prolonged	Hallucination Nos	Other	Accounte		PS		ORAL	
Date: 12/31/1997	ISR Number: 3013345-7	Report Type: Expedited	(15-Day)	Company Report Numbe	r: 91903		Age: 13 YR	Gender: Female
Outcome	PT	Report Source	Product	-			13 IK	Gender: Female
Death	Completed Suicide	Health Professional	Accutane		Role	Manufacturer	Route	Dose/Unit Duration
			Accuaile	<u></u>	PS		ORAL,	
Date: 12/31/1997	ISR Number: 3013358-5	Report Type: Expedited	(15-Day)	Company Report Numbe	- 90195			
Outcome	PΤ	Damant C		, and any and	. 50155		Age: 42 YR	Gender: Female
Other	Depression Nec	Report Source Consumer	Product		Role	Manufacturer	Route	Dose/Unit Duration
	Suicidal Ideation	Consumer	Accutane		PS		ORAL	
			Klonopin		C			
			Trazodone		C			
			Benadryl		C			
Date: 12/31/1997	ISR Number: 3013361-5	Report Type: Expedited	(15-Day)	Company Report Number	r: 91718		Age: 29 YR	Gender: Female
Outcome	PT	Report Source	Product					Gender: Female
Other	Anger	Consumer	Accutane		Role	Manufacturer	Route	Dose/Unit Duration
	Crying	Other	Treestance		PS		ORAL	
	Lip Dry Major Depressive Disorder Nos							
	Visual Disturbance Nos							
Date: 12/31/1997	ISR Number: 3013364-0	Report Type: Expedited	15. Day)					
Outcome	PT			Company Report Number	; 904789		Age: 19 YR	Gender: Male
Hospitalization -	Depression Nec	Report Source	Product		Role	Manufacturer	Route	Dose/Unit Duration
Initial or Prolonged	Hallucination Nos	Other	Accutane	<u> </u>	PS.		ORAL	Dose/Unit Duration
Date: 01/08/1998								
Date: 01/00/1998	ISR Number: 3016841-1	Report Type: Expedited (15-Day)	Company Report Number	: 92130		Age: 38 YR	Gender: Female
Outcome	PT	Report Source	Product		n			Genuer: Female
Hospitalization -	Abnormal Behaviour Nos	Foreign	Roaccutane		Role	Manufacturer	Route	Dose/Unit Duration
Initial or Prolonged	Cognitive Disorder Nec	Other	Cortancyl		PS		ORAL	
	Condition Aggravated Encephalopathy Nos		Solumedroi		SS		ORAL	
	mechaniohami taos		Endoxan		C			
			Synacthene		C			
			Colchicine		С			
	 		Coicnicine		C			

FDA : Adverse Event Reporting System (ALRS) Freedom Of Information (FOI) Report

Date: 01/21/1998	ISR Number: 3017857-1	Report Type: Expedited (15-Day)	Company Report Number	er: 92822	•	Age: 44 YR	Gend	er: Male
Outcome	<u>PT</u>	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
Other	Anxiety Nec	Health Professional	Accutane		PS		ORAL		
	Bipolar Disorder Nec		Prozac		C ·				
	Thinking Abnormal Nec				·				
Date: 01/21/1998	ISR Number: 3017873-X	Report Type: Expedited (15-Day)	Company Report Numb	er: 92735		Age: 18 YR	Gend	er: Male
Outcome	PT	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
Death .	Completed Suicide	Health Professional	Accutane		PS		ORAL		Datation
Date: 01/21/1998	ISR Number: 3017887-X	Report Type: Expedited (15-Day)	Company Report Numb	er: 88218		Age: 16 YR	Gend	er: Male
Outcome	PT	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization -	Aggression	Poreign	Roaccutane		PS			2350 UIII	Parariol
Initial or Prolonged	Amnesia Nec	Health Professional	2000coudite				ORAL		
	Asthenia								
	Dry Skin								
	Hypertension Nos								
	Mucosal Dryness Nos								
	Muscle Cramps								
	Phobias Nec								
	Polydipsia								
	Sweating Increased								
	Tachycardia Nos								
Date: 01/27/1998	ISR Number: 3019417-5	Report Type: Expedited	(15-Day)	Company Report Numb	er: 93114		Age: 32 YR	Gend	er: Pemale
Outcome	PT	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization -	Bronchitis Nos	Consumer	Accutane	•	PS		ORAL		
Initial or Prolonged	Complications Of Maternal						OKAL		
Congenital Anomaly	Exposure To Therapuetic Drugs Growth Retarded								
	Hepatotoxicity Nos								
	Jaundice Nos								
4	Kidney Small								
	Malaise								
	Stammering								
Date: 01/27/1998	ISR Number: 3019422-9	Report Type: Expedited	(15-Day)	Company Report Numi	er: 93037		Age: 16 YR	Gend	er: Male
Outcome	PT	Report Source	Product	<u> </u>	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Abnormal Behaviour Nos	Literature	Accutane		PS		ORAL		
	Aggression	Health Professional	Lsd		SS		OKAL		
	Drug Abuse								

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FDA - Adverse Event Reporting System (AERS) Freedom Of Information (FOI) Report

Date: 01/27/1998	ISR Number: 3019460-6	Report Type: Expedited	(15-Day)	Company Report Number: 930	35	Age: 16 YR	Gender: Male
Outcome Hospitalization - Initial or Prolonged	PT Dystonia Hallucination Nos Paranoia Psychotic Disorder Nos Speech Disorder Nec	Report Source Literature Health Professional	Product Accutane Tetracycline	Role PS	*	Route ORAL ORAL	Gender: Male <u>Dose/Unit</u> <u>Duration</u>
Date: 02/02/1998 Outcome	ISR Number: 3022832-7	Report Type: Expedited Report Source	(15-Day)	Company Report Number: 932		Age: 39 YR	Gender: Male
Other	Dry Skin Hyperthyroidism Aggravated Nervousness Skin Chapped	Consumer	Accutane Tofranil Xanax	PS C C	Manufacturer	Route ORAL	Dose/Unit Duration
Date: 02/09/1998 Outcome	ISR Number: 3026038-7	Report Type: Expedited	-	Company Report Number: 9353	39	Age: 54 YR	Gender: Female
Other	Abdominal Pain Upper Anxiety Nec Back Pain Burning Sensation Nos Calculus Renal Nos	Report Source Consumer	Product Accutane Premarin Tenormin	Role PS C C	Manufacturer	Route	Dose/Unit Duration
	Constipation Ecchymosis Bye Infection Viral Nos Eye Initation Gall Bladder Disorder Nos Haematuria Present						• •
•	Heart Rate Irregular Hepatic Disorder Nos Lethargy Nail Disorder Nos Rash Erythematous Rash Pruritic						
	Skin Discolouration Sore Throat Nos Tic Nec Urine Abnormal Nos Vasculitis Nos	· · · · · · · · · · · · · · · · · · ·					

FDA - Adverse Event Reporting System (AERS) Freedom Of Information (FOI) Report

Date: 01/27/1998	ISR Number: 3019460-6	Report Type: Expedited	(15-Day)	Company Report Number: 930	35	Age: 16 YR	Gender: Male
Outcome Hospitalization - Initial or Prolonged	PT Dystonia Hallucination Nos Paranoia Psychotic Disorder Nos Speech Disorder Nec	Report Source Literature Health Professional	Product Accutane Tetracycline	Role PS	*	Route ORAL ORAL	Gender: Male <u>Dose/Unit</u> <u>Duration</u>
Date: 02/02/1998 Outcome	ISR Number: 3022832-7	Report Type: Expedited Report Source	(15-Day)	Company Report Number: 932		Age: 39 YR	Gender: Male
Other	Dry Skin Hyperthyroidism Aggravated Nervousness Skin Chapped	Consumer	Accutane Tofranil Xanax	PS C C	Manufacturer	Route ORAL	Dose/Unit Duration
Date: 02/09/1998 Outcome	ISR Number: 3026038-7	Report Type: Expedited	-	Company Report Number: 9353	39	Age: 54 YR	Gender: Female
Other	Abdominal Pain Upper Anxiety Nec Back Pain Burning Sensation Nos Calculus Renal Nos	Report Source Consumer	Product Accutane Premarin Tenormin	Role PS C C	Manufacturer	Route	Dose/Unit Duration
	Constipation Ecchymosis Bye Infection Viral Nos Eye Initation Gall Bladder Disorder Nos Haematuria Present						• •
•	Heart Rate Irregular Hepatic Disorder Nos Lethargy Nail Disorder Nos Rash Erythematous Rash Pruritic						
	Skin Discolouration Sore Throat Nos Tic Nec Urine Abnormal Nos Vasculitis Nos	· · · · · · · · · · · · · · · · · · ·					

FDA: Ariverse Event Reporting System (AERS) President Of Information (FOI) Report

Date: 02/10/1998	ISR Number: 3026743-2	Report Type: Expedited (15-Day)	Company Report Number: 93458		Age: 22 YR	Gender: Male
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit Duration
Death	Completed Suicide	Other	Accutane	PS		ORAL	Data Duraum
Date: 02/10/1998	ISR Number: 3026744-4	Report Type: Expedited (15-Day)	Company Report Number: 93625		Age: 16 YR	Gender: Male
Outconse	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit Duration
Death	Completed Suicide	Health Professional	Accutane	PS		ORAL	Dose/Unit Duration
	Depression Nec	Other				OKAL	
Date: 02/12/1998	ISR Number: 3030329-3	Report Type: Expedited (15-Day)	Company Report Number: 94020)	Age: 19 YR	Gender: Female
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit Duration
Other	Candida Nos	Health Professional	Accutane	PS		ORAL	Dose Citt Duration
	Condition Aggravated					OKAL	
	Insomnia Nec Panic Attack						
				 			
Date: 02/12/1998	ISR Number: 3030330-X	Report Type: Expedited	(15-Day)	Company Report Number: 94041	L	Age: 27 YR	Gender: Female
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit Duration
Congenital Anomaly	Chromosomal Abnormality Nos Complications Of Maternal	Health Professional	Accutane	PS		ORAL	
	Exposure To Therapuetic Drugs						
	Down'S Syndrome						
	Premature Labour						
Date: 02/12/1998	ISR Number: 3030332-3	Report Type: Expedited	(15-Day)	Company Report Number: 8390	s .	Age: 18 YR	Gender: Female
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit Duration
Other	Candida Nos	Health Professional	Accutane	PS		ORAL	Total Total Total
	Cephalhaematoma					ÇANL.	
	Chlamydial Infection Nos Congenital Urinary Tract						
	Anomaly Nos						
	Eczema Nos						
	Hydrocele		•				
	Insomnia Nec						
	Panic Attack						
Date: 02/12/1998	ISR Number: 3030336-0	Report Type: Expedited	(15-Day)	Company Report Number: 9143	1	Age: 56 YR	Gender: Female
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit Duration
Other	Benign Eye Neoplasm Nos Chorioretinitis	Health Professional	Accutane	PS		ORAL	Diracon

FDA - Adverse Event Reporting System (AERS) Freedom Of Information (FOD Report

Date: 02/12/1998	ISR Number: 3030339-6	Report Type: Expedited	(15-Day)	Company Report Nu	mber: 93881		Age: 29 YR	Gend	er: Female
Outcome	PT	Report Source	Product		Role	Manufacturer	Route	D	
Other	Abnormal Eye Movements Nos	Consumer	Accutane		PS PS			Dose/Unit	Duration
	Anxiety Nec		Retin A				ORAL		
	Cerebral Oedema				SS		TOPICAL		
	Convulsions Nos		Vitamin A		C				
	Diabetes Mellitus Nos		Vitamin E	•	C				
	Diplopia		Vitamin B		c				
	Dizziness (Exc Vertigo)								
	Epistaxis								
	Fatigue								
	Headache Nos								
	Insomnia Nec								
	Malaise								
	Menstrual Disorder Nos								
	Movement Disorder Nos								
	Muscle Twitching		•	•					
	Nausea				,				
	Nervousness								
	Panic Attack								
	Pyrexia								
	Salivary Hypersecretion								
	Sensation Of Pressure Nos								
	Stress Symptoms								
	Syncope								
	Tremor Nec								
	Vision Blurred								
Date: 02/12/1998	ISR Number: 3030587-5	Report Type: Expedited	(15-Day)	Company Report Nu	nber: 91720		Age: 14 YR	Gende	r: Male
Outcome	PT	Report Source	Product		Role	Manufacturer			
Death	Aspartate Aminotransferase	Health Professional	Accutane		PS		Route	Dose/Unit	Duration
	Increased Blood Alkaline Phosphatase Nos		Bactrim Ds				ORAL		
	Increased		Dactrim Ds		SS		ORAL		
	Blood Lactate Dehydrogenase								
	Increased								
	Blood Triglycerides Increased								
	Completed Suicide								
	Dry Skin								

FDA: Adverse Event Reporting System (AFRS) Freedom Of Information (FOI) Report Date: 02/18/1998 ISR Number: 3031267-2 Report Type: Expedited (15-Day) Company Report Number: 92114 Age: 32 YR Gender: Female Outcome Report Source Hospitalization -Abdominal Pain Nos Manufacturer Dose/Unit Duration Initial or Prolonged Consumer Accutane Bronchitis Nos PS ORAL Health Professional Complications Of Maternal Exposure To Therapuetic Drugs Congenital Abnormality Nos Constipation Growth Retarded Hypermetropia Jaundice Nos Kidney Small Otitis Media Nos Rhinitis Allergic Nos Stammering Date: 02/18/1998 ISR Number: 3031272-6 Report Type: Expedited (15-Day) Company Report Number: 93881 Age: 29 YR Gender: Female Outcome Report Source Product Other Role Manufacturer Anxiety Nec Route Dose/Unit Duration Consumer Accutane Cerebral Oederna PS ORAL Health Professional Convulsions Nos Retin A SS TOPICAL Diabetes Mellitus Nos Vitamin A С Diplopia Vitamin E C Dizziness (Exc Vertigo) Vitamin B Emotional Disturbance Nos Epistaxis Fatigue Headache Nos Hypoglycaemia Nos Increased Activity Insomnia Nec Loss Of Consciousness Nec Malaise Menstrual Disorder Nos Muscle Twitching Nausea Nervousness Panic Attack Pyrexia Salivary Hypersecretion Sedation Sensation Of Pressure Nos

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				Of Information (R		Aspen				
Date: 02/18/1998	ISR Number: 3031286-6	Report Type: Expedited	(15-Day)	Company Report Number: 91	431		Age: 56 YR	Ger	nder: Female	
Ontcome	PT	Report Source	Product			122 1 3	•		remate	
Other	Benign Eye Neoplasm Nos	Health Professional	Accutane	Rel		Manufacturer	Route	Dose/Unit	Duration	
	Chorioretinitis		Accurane	PS			ORAL			
	Clamminess									
	Eating Disorder Nec									
	Eye Inflammation Nos									
	Hypersensitivity Nos									
	Mental Impairment Nos Shivering									
	Tremor Nec									
	Vision Abnormal Nec									
	Vision Blurred									
Date: 02/18/1998										
	ISR Number: 3032237-0	Report Type: Expedited	(15-Day)	Company Report Number: 930	625		Age: 16 YR	Ce	ader: Male	
Outcome	PT	Report Source	Product					04	Mier. Maie	
Death	Completed Suicide	Health Professional		Rol	e	Manufacturer	Route	Dose/Unit	Duration	
	Depression Nec	Other	Accutane	PS			ORAL			
	Dry Skin	Oute								
Date: 02/19/1998	ISR Number: 3032263-1	Report Type: Expedited	ar D							
Outcome		response 13ber 175bernien	(13-Day)	Company Report Number: 931	114		Age: 32 YR	Ger	ider: Female	
	PT	Report Source	Product	Role		Manufacturer	n			
Hospitalization - Initial or Prolonged	Abdominal Pain Nos Bronchitis Nos	Consumer	Accutane	PS		Manuelactatel.	Route	Dose/Unit	Duration	
- I I I I I I I I I I I I I I I I I I I	Complications Of Maternal	Health Professional		rs			ORAL			
	Exposure To Therapuetic Drugs						100			
	Constipation			•						
	Growth Retarded									
	Hypermetropia									
	Jaundice Nos									
	Kidney Small									
	Otitis Media Nos									
	Rhinitis Allergic Nos	-								
	Stammering									
late: 02/19/1998	ISR Number: 3032273-4	Report Type: Expedited	15-Day)	Company Report Number: 938	191	· · · · · · · · · · · · · · · · · · ·				
Outcome	PT	Report Source	Product				Age: 29 YR	Gen	ider: Female	
Other	Anxiety Nec	Consumer		Role	<u>.</u>	Manufacturer	Route	Dose/Unit	Duration	
	Convulsions Nos	Health Professional	Accutane	PS			ORAL			
	Diabetes Mellitus Nos	redui Professional	Retin A	SS			TOPICAL	¥		
	Diplopia		Vitamin A	С						
	Dizziness (Exc Vertigo)		Vitamin E	, c						
08/03/2000	-									

		EDA-		w Event Report		3000 TA 1000				
				Of Information		acan con xxx				
				THE STREET		ROBER				
Date: 02/23/1998	ISR Number: 3035850-X	D								
Outcome		Report Type: Expedited (15-Day)	Company Report Numb	ber: 87461		Age: 35 YR	Ges	ider: Male	
Other	<u>PT</u>	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration	
Outer	Depression Nec Influenza	Consumer	Accutane		PS		ORAL	Dose Citi	Duration	-
	Liver Fatty		Betoptic		С		ORAL			
	Liver Punction Tests Nos		Trusopt		c					
	Abnormal Oesophageal Erosions									
	Pain Nos									
	Pruritus									
Date: 02/23/1998	ISR Number: 3037179-2									
		Report Type: Expedited (15-Day)	Company Report Numb	er: 94423		Age: 13 YR	Gea	ider: Femal	e .
Outcome	PT PT	Report Source	Product		Role	Manufacturer	Route			
Other	Depression Nec Epistaxis	Other	Accutane		PS	ivianulaciulei		Dose/Unit	Duration	-
	Migraine Nos		Chlor-Trin	eton	c		ORAL			
	Mood Swings		Claritin-D		C C					
	Rash Erythematous		Nebulizer		c					
	Vision Blurred									
Date: 02/27/1998	ISR Number: 3037624-2	Report Type: Expedited (5 Davi				······································			
Outcome	PT		.3-Day)	Company Report Numb	er: 94721		Age:	Gen	ıder: Femal	e
Hospitalization -	Abnormal Behaviour Nos	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration	,
Initial or Prolonged	Mania Della viola 140s	Health Professional	Accutane	-	PS					-
			Lithium		C					
Date: 02/27/1998	ISR Number: 3037626-6	Report Type: Expedited (1	5-Day)	Company Report Numb	em 80722					
Outcome	PT			Company Report 14mm	CI: 05/23		Age:	Ger	nder: Femal	e
Disability	Attention Deficit/Hyperactivity	Report Source Other	Product		Role	Manufacturer	Route	Dose/Unit	Duration	
Congenital Anomaly	Disorder	Outer	Accutane		PS					_
Í	Cardiac Disorder Nos Clumsiness									
	Complications Of Maternal									
	Exposure To Therapuetic Drugs									
	Difficulty In Walking Foot Deformity Nos									
	Motor Dysfunction Nos									
Date: 03/02/1998	ISR Number: 3038633-X									
		Report Type: Expedited (1	5-Day)	Company Report Number	er: 94721		Age:	Gen	der: Femal	
Outcome	PT	Report Source	Product		Dolo	Manufacture	=			-
Hospitalization - Initial or Prolonged	Abnormal Behaviour Nos	Health Professional	Accutane		Role PS	Manufacturer	Route	Dose/Unit	Duration	-
of 1 tolougen	Increased Activity Mania				ro		OPHTHAL MIC	•		
08/03/2000	· · · · · · · · · · · · · · · · · · ·							D 160		
							-	Page 169	of 487	

FDA - Adverse Event Reporting System (AERS) Freedom Of Information (FITI) Report Date: 03/03/1998 ISR Number: 3040349-0 Report Type: Expedited (15-Day) Company Report Number: 94940 Age: 16 YR Gender: Female Outcome Report Source Product Other Manufacturer Hallucination Nos Route Dose/Unit Duration Foreign Roaccutane Lyme'S Disease PS ORAL Health Professional Nausea Sedation Taste Disturbance Date: 03/05/1998 ISR Number: 3044287-9 Report Type: Expedited (15-Day) Company Report Number: 93309 Age: Gender: Female Outcome Report Source Product Other Abdominal Pain Upper Role Route Dose/Unit Duration Consumer Back Pain Accutane PS ORAL Jaundice Nos Sleep Disorder Due To General Medical Condition, Mixed Type Date: 03/05/1998 ISR Number: 3050346-7 Report Type: Direct Company Report Number: Age: 16 YR Gender: Female Outcome Report Source Product Other Suicide Attempt Role Manufacturer Route Dose/Unit Duration Accutane PS Date: 03/04/1998 ISR Number: 3050470-9 Report Type: Direct Company Report Number: Age: 18 YR Gender: Female Outcome Report Source Product Hospitalization -Depression Nec Role Manufacturer Route Dose/Unit Duration Initial or Prolonged Accutane Suicide Attempt PS Roche Date: 03/04/1998 ISR Number: 3050493-X Report Type: Direct Company Report Number: Age: 17 YR Gender: Male Outcome Report Source Product Death Completed Suicide Manufacturer Route Dose/Unit Duration Health Professional Accutane PS Date: 03/10/1998 ISR Number: 3054552-7 Report Type: Expedited (15-Day) Company Report Number: 95430 Age: 23 YR Gender: Female Outcome Report Source Product Other Alopecia Manufacturer Route Dose/Unit Duration Blindness Night PS Blood Cholesterol Increased Antidepressants C Blood Pressure Increased Blood Triglycerides Increased Depression Nec Epistaxis Headache Nos

		EDA	- Advers Freedom	Event Reporting Syr Of Information (PO)	teni (A ERS). Report		
Date: 03/10/1998 Outcome	ISR Number: 3054593-X	Report Type: Expeditor	d (15-Day)	Company Report Number: 95291		Age: 19 YR	Gender: Male
Life-Threatening	Depression Nec	Report Source	Product	Role	Manufacturer	Route	Dose/Unit Duration
ū	Non-Accidental Overdose	Consumer	Accutane	PS		ORAL	Data Citte Data Gon
	Overdose Nos Suicide Attempt		Prozac	SS			
Date: 03/10/1998	ISR Number: 3054597-7	Report Type: Expedited	l (15-Day)	Company Report Number: 91162		Age: 17 YR	
Outcome	PT	Report Source	Product			Age. 1/1K	Gender: Male
Life-Threatening	Anxiety Nec	Other	Accutane	Role	Manufacturer	Route	Dose/Unit Duration
	Depression Nec Suicide Attempt		Accurate	PS		ORAL	
Date: 03/10/1998 Outcome	ISR Number: 3054664-8	Report Type: Expedited	(15-Day)	Company Report Number: 95304		Age: 20 YR	Gender: Female
Death	PT PT	Report Source	Product	D.1.		-	Guitari. Temaie
Deam	Completed Spicide Vorniting Nos	Health Professional	Accutane	Role PS	Manufacturer	Route	Dose/Unit Duration
	Volutiong IVOS		Denmlen	rs C		ORAL	
D. 4	· · · · · · · · · · · · · · · · · · ·		Spironolactor	_			
Date: 03/10/1998 Outcome	ISR Number: 3054939-2 PT	Report Type: Expedited	(15-Day)	Company Report Number: 95296		Age: 16 YR	Gender: Male
Hospitalization -	Depression Nec	Report Source	Product	Role	Manufacturer	Route	T
Initial or Prolonged	Suicidal Ideation	Other	Accutane	PS		ORAL	Dose/Unit Duration
Date: 03/10/1998	ISR Number: 3055037-4	P			<u> </u>	OKAL,	4 - 2 - 1
Outcome	PT	Report Type: Expedited	(15-Day)	Company Report Number: 90195		Age: 42 YR	Gender: Female
Other	Depression Nec	Report Source	Product	Role	Manufacturer	Route	-
	Suicidal Ideation	Consumer	Accutane	PS			Dose/Unit Duration
			Klonopin	c		ORAL	
			Trazodone	c			
			Benadryl	c			
ate: 03/10/1998	ISR Number: 3055040-4	Report Type: Expedited	(15-Day)	Company Report Number: 95293		Age: 15 YR	C-1 X
Outcome	PT	Report Source	Product				Gender: Male
ife-Threatening	Overdose Nos	Health Professional	Accutane	Role	Manufacturer	Route	Dose/Unit Duration
	Suicide Attempt	_	Prozac	PS		ORAL	

FDA - Adverse Event Reporting System (AERS) Freedom Of Information (PDI) Report Date: 03/16/1998 ISR Number: 3055125-2 Report Type: Expedited (15-Day) Company Report Number: 95287 Gender: Male Age: 15 YR Outcome PT Report Source Product Role Manufacturer Dose/Unit Duration Route Anorexia Other Other Accutane PS ORAL Depression Nec C Prozac Insomnia Nec Mental Disorder Nec Tic Nec Tourette'S Disorder Date: 03/16/1998 ISR Number: 3055809-6 Report Type: Expedited (15-Day) Company Report Number: 95445 Age: 18 YR Gender: Male Outcome Product Report Source Dose/Unit Duration Abnormal Behaviour Nos Other PS ORAL Aggression SS -Confusion Hostility Lethargy Pallor Social Avoidant Behaviour Weakness Date: 03/16/1998 ISR Number: 3055853-9 Report Type: Expedited (15-Day) Company Report Number: 95448 Age: 27 YR Gender: Female Outcome Report Source Manufacturer Dose/Unit Duration Route Anxiety Nec Other PS Accutane ORAL Depression Nec Dry Eye Nec Dry Skin Lip Dry Panic Attack Date: 03/16/1998 ISR Number: 3055855-2 Report Type: Expedited (15-Day) Company Report Number: 95265 Age: Gender: Male Outcome PT Product Role Dose/Unit Duration Route Abnormal Behaviour Nos Other PS Accutane ORAL Depression Nec Insomnia Nec Suicidal Ideation Date: 03/16/1998 ISR Number: 3055858-8 Report Type: Expedited (15-Day) Company Report Number: 95443 Age: 16 YR Gender: Female Outcome Report Source Product Role Manufacturer Route Dose/Unit Duration Abnormal Behaviour Nos Life-Threatening Other Accutane PS ORAL Drug Abuse Lsd С Mood Swings

		1	teedom	Event Reports Of Information		Keport				
Date: 03/17/1998	ISR Number: 3055879-5	Report Type: Expedited		Company Report Number			Age: 17 YR	Ge	nder: Male	
Death	PT	Report Source	Product					-	- Iviale	
	Abnormal Behaviour Nos	Other	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration	
Life-Threatening	Anorexia		Accidance		PS		ORAL			
Disability	Completed Suicide									
	Depression Nec									
	Mood Swings									
Date: 03/17/1998	ISR Number: 3055884-9	Report Type: Expedited	(15 D)							
Outcome	Typ	Part Type: Expedited	(13-13ay)	Company Report Numbe	r: 95304		Age: 20 YR	Ger	der: Female	
Death	_ <u>PT</u>	Report Source	Product						1 canale	
Death	Completed Suicide	Health Professional	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration	
	Vomiting Nos				PS		ORAL			
			Demnlen		С					
ate: 03/17/1998			Spironolacto	ne	C					
ate: 03/1//1998	ISR Number: 3055918-1	Report Type: Expedited (15-Day)	Company Report Number						
Outcome	PT .			Company Report Numbe	r: 95448		Age: 27 YR	Gen	der: Female	
Other	Anxiety Nec	Report Source	Product		Role	Manufacturer	D	35. 47. 11	_	
	Depression Nec	Consumer	Accutane		PS		Route	Dose/Unit	Duration	
	Dry Eye Nec				15		ORAL			
	Dry Skin									
	Lip Dry									
	Panic Attack									
ite: 03/16/1998	ISR Number: 3055928-4	Report Type: Expedited (·		·
utcome	PT	Port Type: Expedited (13-Day)	Company Report Number	9202001	45001	Age: 37 YR	Gen	der: Male	
eath		Report Source	Product		Data.					
	Alanine Aminotransferase Increased	Consumer	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration	
ospitalization - itial or Prolonged	Antibody Nost Abnormal	Health Professional	, recording C	April 1	PS		ORAL.			
isability	Anxiety Nec			the state of the second						
y	Arthralgia									
	Back Pain									
	Biopsy Peripheral Nerve									
	Abnormal									
	Blood Creatine Phosphokinase									
	Blood Creatine Phosphokinase Increased									
	Blood Creatine Phosphokinase Increased Blood Magnesium Decreased									
	Blood Creatine Phosphokinase Increased Blood Magnesium Decreased Carpal Tunnel Syndrome									
	Blood Creatine Phosphokinase Increased Blood Magnesium Decreased Carpal Tunnel Syndrome Chronic Fatigue Syndrome									
	Blood Creatine Phosphokinase Increased Blood Magnesium Decreased Carpal Tunnel Syndrome Chronic Fatigue Syndrome Completed Suicide									
	Blood Creatine Phosphokinase Increased Blood Magnesium Decreased Carpal Tunnel Syndrome Chronic Fatigue Syndrome									

Date: 03/16/1998	IOD V.		e revoluis	e Event Repor Of Intormati	n (FOI)	Report				
Outcome	ISR Number: 3055942-9	Report Type: Expedit	ed (15-Day)	Company Report Nu	nber: 95384		Age: 27 YR	Gend	ier: Male	
Death	PT Bipolar I Disorder	Report Source	Product	_	Role	Manufacturer	Route	Dose/Unit		
Life-Threatening	Completed Suicide Depression Nec Suicidal Ideation	Other	Accutane		PS		ORAL	Dosevint	Duration	
Date: 03/16/1998	ISR Number: 3055960-0	Report Type: Expedit	ed (15-Day)	Company Report Num	nher: 03530	· · · · · · · · · · · · · · · · · · ·	A 5470		<u>.</u>	
Outcome	PT	Report Source		Tanay enopolerican	iner. 95559		Age: 54 YR	Gend	ler: Female	
Other	Abdominal Pain Nos	Consumer	Product		Role	Manufacturer	Route	Dose/Unit	Duration	
	Anxiety Nec		Accutane		PS		ORAL			
	Arthralgia Back Pain		Premarin		С		. 1			
	Burning Sensation Nos	* .	Tenormin		С					
	Calculus Renal Nos									
	Constipation	,								
	Dry Eye Nec									
	Ecchymosis									
	Erythema Nec Eye Infection Viral Nos									
	Eye Irritation									
	Gall Bladder Disease Nos									
	Haematuria Present									
	Heart Rate Irregular									
	Hepatic Cyst Nos					the second second second				
	Paraesthesia Nec Rash Pruritic									
	Skin Discolouration									
•	Sore Throat Nos	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1								
	Urine Abnormal Nos									
	Vasculitis Nos									
	Vein Pain									
	ISR Number: 3055962-4	Report Type: Expedited	l (15-Day)	Company Report Num	ber: 95341		Age: 17 YR	Gend	ler: Male	
ntcome her	PT	Report Source	Product		D-1-	36				
IRA	Appetite Decreased Bipolar Disorder Nec	Other	Accutane		Role PS	Manufacturer	Route	Dose/Unit	Duration	
	Depression Aggravated				rs		ORAL			
	Mood Alteration Nos									
	Suicidal Ideation							•		
	Weight Decreased									

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Date: 03/16/1998	ISR Number: 3056036-9	Report Type: Expedited		Company Report Number: 9			4			
Outcome	PT	Report Source	5	1 0 p (ambel)	,5555		Age: 18 YR	Gender	: Male	
Death	Completed Suicide	Other	Product	<u>R</u>	ole	Manufacturer	Route	Dose/Unit I	Ouration	
	Non-Accidental Overdose		Accutane	P	S					
Date: 03/16/1998	ISR Number: 3056037-0	Report Type: Expedited	(IS Daw)	_			· · · · · · · · · · · · · · · · · · ·			
Outcome	PT		(13-Day)	Company Report Number: 9	5333		Age: 18 YR	Gender	: Male	
Death	Completed Suicide	Report Source	Product	R	ole	Manufacturer	Route	D		
-	Non-Accidental Overdose	Other	Accutane	PS				Dose/Unit I	Duration	
	Suicide Attempt						ORAL			
Date: 03/18/1998	ISR Number: 3056373-8	- P								
Outcome		Report Type: Direct		Company Report Number:			Age: 16 YR	Gender	: Male	
	PT	Report Source	Product	.				Genaci	· iviale	
Required Intervention to Prevent Permanent	n Depression Nec		Accutane	PS	<u>ole</u>	Manufacturer	Route	Dose/Unit I	uration	
mpairment/Damage	<u> </u>			ra	5		ORAL .			
ate: 03/19/1998	ISR Number: 3057782-3	D		· · · · · · · · · · · · · · · · · · ·						
Outcome		Report Type: Direct		Company Report Number:			Age:	Gender	Female	
Other	PT P	Report Source	Product	D.	.1.	March 4				
outer	Depression Nec		Accutane	PS	ole	Manufacturer	Route	Dose/Unit D	uration	
ate: 03/19/1998	ISR Number: 3057827-0			rs		Roche				
	15K Number: 303/82/-0	Report Type: Expedited	(15-Day)	Company Report Number: 95	5976		Age: 18 YR			
Outcome	PT	Report Source	Product				rige. 10 IK	Gender	Male	
lospitalization - nitial or Prolonged	Anxiety Nec	Other	Accutane	Ro		Manufacturer	Route	Dose/Unit D	uration	
and of Frotoliged	Cerebrovascular Accident Nos Convulsions Nos		Accutane	PS			ORAL			
	Coordination Abnormal Nos		1.79							
	Diplopia	· · · · · · · · · · · · · · · · · · ·								
	Disability Nos									
	Dysarthria									
	Eye Movement Disorder Nos									
	Inflammation Nos									
	Vascular Disorder Nos									
	Vision Blurred					•				
te: 03/24/1998	ISR Number: 3058987-8	Report Type: Expedited (15-Day)	Company Perced No	064					
utcome	PT		• • • • • • • • • • • • • • • • • • • •	Company Report Number: 95	864		Age: 21 YR.	Gender	Male	
spitalization -	Delirium	Report Source	Product	Rol	le	Manufacturer	Route	Dose/Unit D	uration	
tial or Prolonged		Foreign	Roaccutane	PS				- Joseph D	er anon	

		FDA T	Advers readon	e Event Reportin Di Information (e Sin FOL	tem (AERS) Repart			
Date: 03/12/1998 Outcome	ISR Number: 3059142-8 PT	Report Type: Direct Report Source	Product	Company Report Number:			Age: 15 YR	Gender: Fem	ale
Life-Threatening	Depression Nec				Role	Manufacturer	Route	Dose/Unit Duration	
Hospitalization -	Ear Haemonthage		Accutane	1	PS	Hoffman La Roche	ORAL		
Initial or Prolonged	Epistaxis								
	Lip Dry								
	Rectal Bleeding Suicidal Ideation								
D (00 H = 11 + 1									
Date: 03/12/1998	ISR Number: 3059190-8	Report Type: Direct			·				
Outcome	PT			Company Report Number:			Age: 15 YR	Gender: Male	
Required Intervention	Depression Nec	Report Source	Product	1	Role	Manufacturer	-		•
to Prevent Permanent	- divergett 1460	Consumer	Accutane		PS	Manufacturer	Route	Dose/Unit Duration	_
Impairment/Damage			Serzone		2		ORAL		
Date: 03/12/1998	ISR Number: 3059197-0	Domest 73. D.							
Outcome		Report Type: Direct		Company Report Number:			Age: 17 YR	Gender: Male	
	PT	Report Source	Product					Gender: Male	:
Other	Anger	Consumer	Accutane	_	Role	Manufacturer	Route	Dose/Unit Duration	
	Anxiety Nec		Accuant	P	es	Roche			_
	Appetite Decreased								
	Crying Depression Nec								
Pate: 03/24/1998	ISR Number: 3059391-9	Report Type: Expedited (1:	(Day)						
Dutcome	PT		. 249)	Company Report Number:	96389		Age:	Gender: Fema	de
lospitalization -	Anorexia Nervosa	Report Source	Product	R	Role	Manufacturer	Apartial de la companya de la compan	2 32 3 3 3 3 4 4 5	
nitial or Prolonged	Nausea	Health Professional	Accutane				Route	Dose/Unit Duration	_
nte: 03/24/1998	IOD N		3.535				ORAL		
35,24,1998	ISR Number: 3059394-4	Report Type: Expedited (15	-Day)	Company Report Number: 9	V6202				
utcome	₽T			Company report Number: 9	0392		Age:	Gender: Fema	le
ther	Anorexia Nervosa	Report Source	Product	R	ole	Manufacturer	Route		
	Breast Lump Nos	Foreign	Roaccutan	Pi			Koute	Dose/Unit Duration	_
	Lymphadenopathy	Health Professional		1.					
	Nausea								
	Skin Cysts Nos								
te: 03/24/1998	SR Number: 3059463-9								
_	~~ 1 mintuer: 3039463-9	Report Type: Expedited (15	·Day)	Company Report Number: 9	1070007	1001	 		
utcome	PT	Report Source	T		10,000/	1001	Age: 17 YR	Gender: Male	
ath	Completed Suicide	Foreign	Product		ole	Manufacturer	Route	Dose/Unit Duration	
fe-Threatening	Depression Nec	•	Roaccutane	PS	3			Dose/Unit Duration	-
		Literature							

Adverse Event Reporting System (AERS reedom Of Information (PER) Report Date: 03/24/1998 ISR Number: 3059492-5 Report Type: Expedited (15-Day) Company Report Number: 96225 Outcome Age: 37 YR Gender: Female Report Source Product Other Hypersomnia Role Manufacturer Dose/Unit Duration Route Consumer Accutane Hypothyroidism PS ORAL Pruritus Zoloft С Urticaria Nos Weight Increased Date: 03/24/1998 ISR Number: 3059494-9 Report Type: Expedited (15-Day) Company Report Number: 91903 Outcome Age: 13 YR Gender: Female Report Source Product Death Cheilitis Role Manufacturer Route Health Professional Dose/Unit Duration Accutane Completed Suicide PS ORAL Date: 03/24/1998 ISR Number: 3059498-6 Report Type: Expedited (15-Day) Company Report Number: 96084 Outcome Age: 16 YR Gender: Male Report Source Other Condition Aggravated Product Role Manufacturer Route Dose/Unit Duration Other Accutane Depression Aggravated PS ORAL Zoloft Dry Eye Nec C Hypertriglyceridaemia Artificial Tears С Lip Dry Obsessive-Compulsive Disorder Date: 03/24/1998 ISR Number: 3059502-5 Report Type: Expedited (15-Day) Company Report Number: 96185 Age: 18 YR Outcome Gender: Male Report Source Product Other Asthma Nos Role Manufacturer Route Dose/Unit Duration Cough Accutane PS ORAL Depression Nec Epistaxis Lethargy Weakness Date: 03/24/1998 ISR Number: 3059554-2 Report Type: Expedited (15-Day) Company Report Number: 96110 Outcome Age: 26 YR Gender: Female Report Source Hospitalization -Product Depression Aggravated Role Manufacturer Route Initial or Prolonged Dose/Unit Duration Health Professional Depression Nec Accutane PS ORAL Muscle Spasms Paxil C Ovarian Disorder Nos

		FDA	- Advers Fruedom	e Event Reportin Of Information (stem (AERS) Report				
Date: 03/24/1998 Outcome	ISR Number: 3059555-4	Report Type: Expedite	ed (15-Day)	Company Report Number	96187		Age: 21-YR	Ge	nder: Male	
Other	PT Abnormal Behaviour Nos	Report Source	Product		Role	Manufacturer	. .			
out.	Antisocial Personality Disorder	Other	Accutane		PS	Manufacturer	Route	Dose/Unit	Duration	
	Nec				го		ORAL			
	Dry Skin									
	Economic Problem Nos									
	Educational Problem									
	Headache Nos									
	Hypersonnia									
	Impulsive Behaviour Nos									
Date: 03/24/1998	ISR Number: 3059572-4	Report Type: Expedite	1/IED							
Outcome	PT		1 (13-Day)	Company Report Number:	860200	853001	Age: 17 YR	Ger	ider: Male	
Death		Report Source	Product		Role		_			
· · · · ·	Completed Suicide Depression Nec	Other	Accutane			Manufacturer	Route	Dose/Unit	Duration	
Life-Threatening	Eating Disorder Nec				PS		ORAL		*	
Disability	Feeling Abnormal									
	Mood Swings									
Date: 03/24/1998										
	ISR Number: 3059577-3	Report Type: Expedited	(15-Day)	Company Report Number:	94721		•			
Outcome	PT	Report Source					Age:	Gen	der: Female	
Hospitalization -	Abnormal Behaviour Nos	Health Professional	Product		Role	Manufacturer	Route	Dose/Unit	Duration	
nitial or Prolonged	Hallucination Nos	Treatui Professional	Accutane	- I	PS		ORAL		D'ILLUIDI	
	Mania		Lithium		SS					
	Psychotic Disorder Nos		2 F. H.		100		ORAL			
	Self Mutilation									
ate: 03/24/1998	ISR Number: 3060187-2	December 1					<u> 1 tyst y e y y e</u>			
utcome		Report Type: Expedited	(15-Day)	Company Report Number:	94423		Age: 13 YR	Gen	der: Female	_
	PT	Report Source	Product					Gui	uer, remaie	
ther	Depression Nec	Health Professional	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration	
	Dermatitis Nos	Other			S		ORAL			
	Epistaxis		Chlor-Trimet	ion (:					
	Insomnia Nec		Claritin-D	C	:					
	Migraine Nos Mood Swings		Nebulizer	C	:					
	Suicidal Ideation		Zoloft	c	!					

dverse Event Reporting System (AERS) Freedom Of Information (FOI) Report Date: 03/24/1998 ISR Number: 3060188-4 Report Type: Expedited (15-Day) Company Report Number: 94704 Age: 29 YR Gender: Female Outcom PT Report Source Other Acne Nos Role Manufacturer Route Dose/Unit Duration Consumer Accutane Dry Eye Nec PS ORAL Health Professional Headache Nos Imitrex С Insomnia Nec Synthroid C Migraine Aggravated Photophobia Vision Blurred Date: 03/24/1998 ISR Number: 3060298-1 Report Type: Expedited (15-Day) Company Report Number: 95287 Age: 15 YR Gender: Male Outcome Report Source Product Other Appetite Decreased Role Manufacturer Route Dose/Unit Duration Other Depression Nec Accutane PS ORAL Insomnia Nec Prozac (Fluoxetine) С Mental Disorder Nec Serzone (Nefazodone Hydrochloride) Tic Nec Tourette'S Disorder Weight Decreased Date: 03/31/1998 ISR Number: 3060332-9 Report Type: Expedited (15-Day) Company Report Number: 96390 Age: 20 YR Outcome Gender: Male Report Source Product Other Amnesia Nec Role Manufacturer Route Dose/Unit Duration Health Professional Accutane PS ORAL Minocin C Date: 03/26/1998 ISR Number: 3060376-7 Report Type: Expedited (15-Day) Company Report Number: 95293 Age: 15 YR Ontcome Gender: Male Report Source Product Life-Threatening Overdose Nos Role Manufacturer Route Health Professional Dose/Unit Duration Accutane Suicide Attempt PS ORAL. Prozac С Date: 04/03/1998 ISR Number: 3060773-X Report Type: Expedited (15-Day) Company Report Number: 96389 Age: 23 YR Outcome Gender: Female Report Source Hospitalization -Initial or Prolonged Product Anorexia Nervosa Role Route Health Professional Dose/Unit Duration Depression Aggravated Accutane PS ORAL Eating Disorder Nec Claritin C Nausea Paxil C Weight Decreased Ortho Tri Cyclen С Xanax С Ritalin C

Date: 04/03/1998		IUA I	Adverse Rectors (Event Il Infor	Reportit matter	0 595 3001	tem (ATRS) Report				
Outcome	ISR Number: 3060778-9	Report Type: Expedited	(15-Day)	Company R	eport Number	r: 8701030	027001	Age: 18 YR	Gender:	Male	
Life-Threatening	PT Bone Pain Dry Skin Headache Nos Pamesthesia Nec Pruritus Rash Scaly Sedation Speech Disorder Nec Suicide Attempt	Report Source Foreign Literature	Product Roaccutane Oxazepam Doxepin Hyd Methylpredni Erythromycin	solone		Role PS C C C C	Manufacturer	Route ORAL	Dose/Unit Dur		
Date: 04/07/1998	ISR Number: 3061694-9	Report Type: Expedited ((15_Day)								
Outcome Hospitalization - Initial or Prolonged	PT Abnormal Behaviour Nos Confusion Coordination Abnormal Nos Disorientation Dizziness (Exc Vertigo) Electroencephalogram Abnormal Encephalopathy Nos Facial Palsy Hypersomnia Hyperventilation	Report Source Foreign Health Professional	Product Roaccutane Agyrax Vogalene	Company	eport Number	Role PS C C	Manufacturer	Route ORAL	Gender: <u>Dose/Unit</u> <u>Dur</u>	Male ation	
Pate: 04/07/1998	Influenza Like Illness			<u>ing Taraba</u>	Made at	E Wiles	grann (generial) d				
Outcome Disability	ISR Number: 3061704-9 PT Abnormal Eye Movements Nos	Report Type: Expedited () Report Source	15-Day) Product	Company Re	port Number	72202 Role	Manufacturer	Age: 24 YR	Gender: Dose/Unit Dur	Female ation	
Congenital Anomaly	Blindness Transient Cerebral Palsy Conjunctivitis Nec Convulsions Nos Developmental Delay Nos Dyskinesia Nec	Health Professional	Accutane Prozac Alcohol		-	PS C C		ORAL	Dur	neeUII	
·	Dyskinesia Nec Eyelid Ptosis Hyperplasia Nos Hypotonia Irritability Multiple Congenital Abnormalities Mydriasis					:					

		FDA	Series	e Event Reporting		tem (AEUS)				
Date: 03/31/1998 Outcome Death	ISR Number: 3063222-0 PT Completed Suicide Depression Nec Feding Of Despair	Report Type: Direct Report Source Consumer	Product Accutane	Company Report Number:	ole	Manufacturer Hoffman-Laroche	Age: 16 YR Route	Gend	ler: Male Duration	
Date: 04/16/1998	ISR Number: 3064753-X	Report Type: Expedited (15-Day)	Company Report Number: 9	5445		Age: 18 YR			
Outcome	PT	Report Source	Product	•			Mgs. 10 IK	Gend	ler: Male	
Other	Aggression	Other	Accutane		ole	Manufacturer	Route	Dose/Unit	Duration	
	Belligerence Depression Nec		Mescaline	PS			ORAL			
	Disturbance In Social Behaviour Nos Drug Abuse Educational Problem Hostility Lethargy		Mascaille	SS	3					
	Pallor Pallor Social Avoidant Behaviour Weakness									
Date: 04/16/1998	ISR Number: 3064755-3	Report Type: Expedited (1	5-Day)							
Outcome	PT			Company Report Number: 95	5261		Age:	Gend	er: Female	
Required Intervention		Report Source	Product	Ro	le	Manufacturer	Route	Dose/Unit	Duration	
to Prevent Permanent Impairment/Damage	Genital Pain Female Vulval Ulceration Vulvitis	Health Professional	Accutane Loestrin	PS C			ORAL		<u> </u>	
	Vulvovaginal Discomfort									
ate: 04/15/1998	ISR Number: 3066241-3	Report Type: Expedited (1	5-Day)	Company Report Number: 97	7351				 -	
Outcome	PT	Report Source	D 1 1	I J Perstrumber, 57	331		Age: 17 YR	Gende	r: Male	
Other	Accident Nos	Health Professional	Product Accutane	Ro	_	Manufacturer	Route	Dose/Unit	Duration	
	Loss Of Consciousness Nec Mood Alteration Nos Weight Decreased		Ampicillin	PS C			ORAL			
ate: 04/21/1998	TOD N	Report Type: Expedited (13	5-Day)	Company Report Number: 91	162					
Outcome	PT	Report Source		t was suchare transpert; 31	102		Age: 21 YR	Gende	r: Male	
ife-Threatening	Anxiety Nec Depression Nec	Other	Product Accutane	Roll PS	<u>le</u>	Manufacturer	Route	Dose/Unit	Duration	

		F	rie dom	e Event Reporti Of Information		Report			
Date: 04/27/1998	ISR Number: 3069022-X	Report Type: Expedited (15-Day)	Company Report Numb	er: 97796		Age: 16 YR	Gender:	
Outcome	PT	Report Source	D 1 - 4				age. 10 IK	Gender:	Female
Other	Anorexia	Other	Product		Role	Manufacturer	Route	Dose/Unit Du	ration
	Anxiety Nec	Outer	Accutane		PS		ORAL		
	Depression Nec								
	Fibromyalgia Syndrome								
	Gastrointestinal Candidiasis								
	Giardiasis								
	Myalgia								
	Sleep Disorder Nos								
	Weight Decreased								
Date: 04/27/1998	ISR Number: 3070608-7	Report Type: Expedited ((5-Day)	Company Report Number	06200				-,
Outcome	·PT			company report rumm	:F: 90390		Age: 20 YR	Gender:	Male
Other	Amnesia Nec	Report Source	Product		Role	Manufacturer	Route	Dose/Unit Du	ration
	Fear, Focus Nec	Health Professional	Accutane		PS		ORAL,		- auton
			Minocin		C.		OKAL,		
ate: 04/16/1998	ISR Number: 3070773-1	Denote To To the second							
Outcome		Report Type: Expedited (1	.5-Day)	Company Report Number	ar: 97439		Age: 25 YR	Gender:	Female
	PT	Report Source	Product				_		
ther	Abdominal Pain Nos	Consumer			Role	Manufacturer	Route	Dose/Unit Du	ration
	Acne Aggravated	· -	Accutane		PS		ORAL		
	Cholelithiasis								
	Complications Of Maternal								
	Exposure To Therapuetic Drugs Congenital Hearing Disorder								
	Flatulence	The state of the	1.19/	The first beauti	Section 2		The second section		
	Headache Nos		J. 4.						
	Speech Disorder								
	(Developmental)								
te: 04/30/1998	ISR Number: 3071512-0	Report Type: Expedited (1	5 Days		<u> </u>	· · · · · · · · · · · · · · · · · · ·	· · · · · · · · · · · · · · · · · · ·		
utcome	PT		J-Day)	Company Report Number	r: 92223		Age: 17 YR	Gender:	Female
ther	Anorexia Nervosa	Report Source	Product		Role	Manufacturer	Route	Dose/Unit Du	
	Appetite Decreased	Foreign	Roaccutane		PS			DOSO CHIL DI	ration
	Condition Aggravated	Health Professional		hinyl Estradiol/Gestodene)			ORAL		
				umyi Estradioi/Gestodene)	SS		ORAL		
	Cyanosis Peripheral		Stimycine		C .				
	Peripheral Vascular Disease Nos		(Erythromyc	cin)	С				
	Raynaud'S Phenomenon Rigors								

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Date: 04/30/1998	ISR Number: 3071514-4	Report Type: Expedited (15-Day)	Company Report Number: 9	96389		Age: 23 YR	Gender	- F	
Outcome Hospitalization -	PT Anorexia Nervosa	Report Source	Product		lole	Manufacturer	Route			
Initial or Prolonged	Depression Aggravated	Health Professional	Accutane	P			ORAL	Dose/Unit I	Ouration	
*	Eating Disorder Nec		Claritin	С			OKAL			
	Nausea		Paxil	С	:					
	Weight Decreased		Ortho Tri C	yclen C	!					
			Xanax	c	!					
			Ritalin	· c		•				
Date: 04/30/1998	ISR Number: 3071521-1	Report Type: Expedited (1	5-Day)	Company Report Number: 9						
Outcome	PT		• •	Company Report Number: 9	8139		Age:	Gender	: Female	
Hospitalization -	Cellulitis	Report Source Health Professional	Product	R	ole	Manufacturer	Route	Dose/Unit D	Ouration	-
Initial or Prolonged	Depression Nec	rieaun Professional	Accutane	PS	S		ORAL			ļ
	Infection Nos									
	Inflammation Nos Mood Swings									
Date: 04/30/1998										
Date: 04/30/1998	ISR Number: 3073227-1	Report Type: Direct		Company Report Number:			A			
Outcome	_ PT	Report Source		, Jany and a serial			Age: 16 YR	Gender	Male	
Hospitalization -	Abnormal Behaviour Nos	Acport Source	Product	Re-	ole	Manufacturer	Route	Dose/Unit D	uration	
Initial or Prolonged Other	Depression Nec		Accutane	PS	3					.
Other	Mental Disorder Nec									
	Mood Swings		250	Land Bridge-Feb		Company of the second	Agonia wasan sana			İ
Date: 05/05/1998	ISR Number: 3073596-2	Report Type: Expedited (1:	5-Day)	Company Report Number: 9	ć00.4					
Outcome	PT			Company Report Number: 90	0084		Age: 16 YR	Gender	: Male	
Other	Blood Triglycerides Increased	Report Source Other	Product	Ro	ole	Manufacturer	Route	Dose/Unit D	uration	- 1
	Condition Aggravated	Other	Accutane	PS	3		ORAL			1
	Depression Aggravated		Zoloft	, C						ĺ
	Dry Eye Nec		Artificial Tea	rs C						İ
	Lip Dry					•				l
Date: 05/05/1998	Obsessive-Compulsive Disorder									
ase, 03/03/1998	ISR Number: 3073795-X	Report Type: Expedited (15	i-Day)	Company Report Number: 98	3139		Amer	~		
Outcome	PT	Report Source	Product				Age:	Gender	Female	-
Tospitalization -	Cellulitis	Health Professional	Accutance	Ro Ro	_	Manufacturer	Route	Dose/Unit D	uration	- 1
nitial or Prolonged	Depression Nec	Other	Accurance	PS			ORAL	_		
	Mood Swings Skin Infection Nos									
	ONIT INTECTION NOS									

			Prædom	Event Reportin Of Information :		Kepert			
Date: 05/05/1998	ISR Number: 3073845-0	Report Type: Expedite	ed (15-Day)	Company Report Number	. 09222				
Outcome	PT	Report Source		- ampany responsive	. 90332		Age: 80 YR	Gen	der: Male
Other	Abnormal Behaviour Nos	Other	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Aggression	Other	Tasmar		PS		ORAL		
	Dementia Nos Aggravated		Sinemet		C				
	Euphoric Mood		Zoloft		C				
	Hypersomnia		Imdur		С				
	Weight Decreased		Lanoxin		C				
			Folic Acid		c				
		•	K-Dur		c	,			
			Vitamin E		~				
			Feosol		С				
					С				
			Vitamin B1		С				
			Vitamin B12	!	С				
			One-A-Day		С				
			Ecotrin		c ·				
ite: 05/05/1998	ISR Number: 3073852-8	Report Type: Expedited	(15-Dav)	C					
utcome	PT		\ 	Company Report Number:	98380		Age: 63 YR	Gen	der: Male
ospitalization -	Disorientation	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
tial or Prolonged	Hepatic Encephalopathy	Health Professional	Tasmar		PS	-	ORAL	Dogo Cint	Duracion
	Hepatitis Nos		Sinemet		c ·		OKAL		
	Jaundice Nos		Vitamin E		c				
	Liver Function Tests Nos			and the second second	•				
	Abnormal								
	Pancreatic Carcinoma Nos Pyrexia								
	Tremor Nec								
	White Blood Cell Count								
	Decreased Count								
e: 04/30/1998	ISR Number: 3073944-3								
		Report Type: Direct		Company Report Number:			Age:	Gene	der: Female
tcome	PT	Report Source	Product					Gen	uer: remaie
uired Intervention revent Permanent	Anxiety Nec		Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
airment/Damage	Depressed Mood		Accutane	1	PS	Roche			
	Depression Nec								
	Diarrhoea Nos								
	Disturbance In Attention Nec								
	Faecal Occult Blood								
	Irritability								

	Asthma Nos Cough		Accutane		PS	Hoffman Laroche, Inc	Konte.	Dose/Unit Durat	ion
Outcome	PT Andrew V	Report Source	Product		Role	Manufacturer	Route		
ate: 04/29/1998	ISR Number: 3078877-4	Report Type: Direct		Company Report Number		· · · · · · · · · · · · · · · · · · ·	Age: 18 YR	Gender:	Male
		Health Professional	Sinemet		PS C		ORAL		
Other	Abnormal Behaviour Nos	Foreign	Tasmar		Role	Manufacturer	Route	Dose/Unit Durat	íon
utcome	PT	Report Source	Product				-		Male
ate: 05/12/1998	ISR Number: 3076718-2	Report Type: Expedited (1	(5-Day)	Company Report Number	98567		Age: 47 YR	C-1	
	Completed Suicide Depression Nec				PS				
Death	Abnormal Behaviour Nos	- Keport Source	Product Accutane		Role	Manufacturer	Route	Dose/Unit Durat	ion
Outcome	PT	Report Source		Company Report Number			Age: 19 YR	Gender:	Male
ate: 05/13/1998	ISR Number: 3075587-4	Report Type: Direct	*	Company Report Number	-		·		
	Impulsive Behaviour Nos Intermittent Explosive Disorder Loss Of Employment Social Avoidant Behaviour			e e					
~ 	Economic Problem Nos Headache Nos								
Disability Other	Anger Asocial Behaviour		Accutane		Role PS	Manufacturer	Route	Dose/Unit Durat	ion
Outcome	PT	Report Source	Product		D-I-	34			
Date: 04/21/1998	ISR Number: 3074823-8	Report Type: Direct		Company Report Number		——————————————————————————————————————	Age: 20 YR	Gender:	Male
	Gonorrhoea Nos Urethral Discharge Nos	Total Totasiona	Accutane		PS		ORAL		
Other	Depression Nec	Report Source Health Professional	Product		Role	Manufacturer	Route	Dose/Unit Durat	ion
Date: 04/30/1998 Outcome	ISR Number: 3074426-5	Report Type: Expedited (15-Day)	Company Report Number	92643		Age: 17 YR	Gender:	Male
Initial or Prolonged	Diarrhoea Haemorrhagic	Foreign Health Professional	Roaccutane		PS C		ORAL	-	
Hospitalization -	PT Colitis Nos	Report Source	Product		Role	Manufacturer	Route	Dose/Unit Durat	tion
Outcome	ISR Number: 3073952-2	Report Type: Expedited ((15-Day)	Company Report Number	: 68417		Age: 41 YR	Gender:	

08/03/2000

FDA - Adverse Event Reporting System (AFRS) Freedom Of Information (FCI) Report Date: 05/15/1998 ISR Number: 3079356-0 Report Type: Expedited (15-Day) Company Report Number: 94423 Age: 13 YR Gender: Female Outcome Report Source Product Role Manufacturer Route Dose/Unit Duration Other Depression Nec Health Professional Accutanc PS Epistaxis ORAL Other Chlor-Trimeton С Insomnia Nec Claritin Migraine Nos С Mood Swings Nebulizer С Rash Maculo-Papular Zoloft Vision Blurred Date: 05/15/1998 ISR Number: 3079361-4 Report Type: Expedited (15-Day) Company Report Number: 98139 Age: 20 YR Gender: Female Outcome Report Source Role Hospitalization -Initial or Prolonged Manufacturer Dose/Unit Duration Cellulitis Route Health Professional Accutane PS Depression Nec ORAL . Other Epistaxis Inflammation Nos Localised Infection Mood Swings Pyrexia Date: 05/15/1998 ISR Number: 3079381-X Report Type: Expedited (15-Day) Company Report Number: 94704 Age: 29 YR Gender: Female Outcome Report Source Product Acne Aggravated Role Manufacturer Other Dose/Unit Duration Accutane Drug Ineffective PS ORAL Health Professional Imitrex Dry Eye Nec C Synthroid Headache Nos C Insomnia Nec Migraine Aggravated Nausea Photophobia Vision Blurred Date: 05/15/1998 ISR Number: 3079458-9 Report Type: Expedited (15-Day) Company Report Number: 97351 Age: 17 YR Gender: Male Outcome Report Source Product Role Dose/Unit Duration Other Accident Nos Health Professional Accutane Loss Of Consciousness Nec PS ORAL Ampicillin Mood Alteration Nos С Weight Decreased

		FDA	Adver-	e Event Report Of Information	(6)) S.V.	tem (AERS)		
Date: 05/20/1998	ISR Number: 3080382-6	Report Type: Direct				керип		
Outcome	PT			Company Report Numb	ber:		Age:	Gender: Male
Hospitalization -	Abnormal Behaviour Nos	Report Source	Product		Role	Manufacturer	Route	
Initial or Prolonged	Mental Disorder Nec	•	Accutane		PS		Route	Dose/Unit Duration
Disability	Schizophrenia Nos				13			
Required Intervention								
to Prevent Permanent								
Impairment/Damage								
Date: 05/06/1998	ISR Number: 3080757-5	D						
		Report Type: Direct		Company Report Numb	er:		Age:	Gender: Female
Dutcome	PT	Report Source	Product					Gender: Pemale
Iospitalization -	Appetite Decreased				Role	Manufacturer	Route	Dose/Unit Duration
nitial or Prolonged	Depression Nec		Accutane		PS			
	Fatigue					*		
	Mental Impairment Nos							
	Nervousness							
	Suicidal Ideation							
ate: 05/20/1998	ISR Number: 3081102-1	Day 4 70 27 11 4						
		Report Type: Expedited	(15-Day)	Company Report Numb	er: 98350		Age: 42 YR	Gender: Female
utcome	PT	Report Source		Company Report Numb			-	Gender: Female
utcome	PT Abdominal Pain Upper		Product	Company Report Numb	Role	Manufacturer	Age: 42 YR	Gender: Female Dose/Unit Duration
utcome	PT Abdominal Pain Upper Anxiety Nec	Report Source	Product Accutane	Company Report Numb	Role PS	Manufacturer	-	
utcome	PT Abdominal Pain Upper Anxiety Nec Breast Pain	Report Source	Product Accutane Loestrin	Company Report Numb	Role	Manufacturer	Route	
utcome	PT Abdominal Pain Upper Anxiety Nec Breast Pain Diplopia	Report Source	Product Accutane Loestrin Humulin	Company Report Numb	Role PS	Manufacturer	Route	
utcome	PT Abdominal Pain Upper Anxiety Nec Breast Pain Diplopia Disorientation	Report Source	Product Accutane Loestrin	Company Report Numb	Role PS C	Manufacturer	Route	
utcome	PT Abdorninal Pain Upper Anxiety Nec Breast Pain Diplopia Disorientation Dizziness (Exc Vertigo)	Report Source	Product Accutane Loestrin Humulin	Company Report Numb	Role PS C	Manufacturer	Route	
utcome	PT Abdominal Pain Upper Anxiety Nec Breast Pain Diplopia Disorientation Dizziness (Exc Vertigo) Dry Skin	Report Source	Product Accutane Loestrin Humulin Axid	Company Report Numb	Role PS C C C	Manufacturer	Route	
utcome	PT Abdominal Pain Upper Anxiety Nec Breast Pain Diplopia Disorientation Dizziness (Exc Vertigo) Dry Skin Feeling Abnormal	Report Source	Product Accutane Loestrin Humulin Axid Propulsid Lotensin	Company Report Numb	Role PS C C C C	Manufacturer	Route	
utcome	PT Abdorninal Pain Upper Anxiety Nec Breast Pain Dispolentation Dispolentation Dizziness (Exc Vertigo) Dry Skin Feeling Abnormal Headache Nos	Report Source	Product Accutane Loestrin Humulin Axid Propulsid Lotensin Norvasc	Company Report Numb	Role PS C C C C C C	Manufacturer	Route	
utcome	PT Abdorninal Pain Upper Anxiety Nec Breast Pain Diplopia Disorientation Dizziness (Exc Vertigo) Dry Skin Feeling Abnormal Headache Nos Headache Nos	Report Source	Product Accutane Loestrin Humulin Axid Propulsid Lotensin	Company Report Numb	Role PS C C C C	Manufacturer	Route	
utcome	PT Abdominal Pain Upper Anxiety Nec Breast Pain Diplopia Disorientation Dizziness (Exc Vertigo) Dry Skin Feeling Abnormal Headache Nos Headache Nos Aggravated Hypertension Nos	Report Source	Product Accutane Loestrin Humulin Axid Propulsid Lotensin Norvasc	Company Report Numb	Role PS C C C C C C	Manufacturer	Route	
utcome	PT Abdominal Pain Upper Anxiety Nec Breast Pain Diplopia Disorientation Dizziness (Exc Vertigo) Dry Skin Feeling Abnormal Headache Nos Headache Nos Aggravated Hypertension Nos Lip Dry	Report Source	Product Accutane Loestrin Humulin Axid Propulsid Lotensin Norvasc	Company Report Numb	Role PS C C C C C C	Manufacturer	Route	
utcome	Abdorninal Pain Upper Anxiety Nec Breast Pain Diplopia Disorientation Dizziness (Exc Vertigo) Dry Skin Feeding Abnormal Headache Nos Headache Nos Aggravated Hypertension Nos Lip Dry Tachycardia Nos	Report Source	Product Accutane Loestrin Humulin Axid Propulsid Lotensin Norvasc	Company Report Numb	Role PS C C C C C C	Manufacturer	Route	
Jutcome	Abdominal Pain Upper Anxiety Nec Breast Pain Diplopia Disorientation Dizziness (Exc Vertigo) Dry Skin Feeling Abnormal Headache Nos Headache Nos Aggravated Hypertension Nos Lip Dry Tachycardia Nos Tongue Cedema	Report Source	Product Accutane Loestrin Humulin Axid Propulsid Lotensin Norvasc	Company Report Numb	Role PS C C C C C C	Manufacturer	Route	
Outcome Other	PT Abdominal Pain Upper Anxiety Nee Breast Pain Diplopia Disorientation Dizziness (Exc Vertigo) Dry Skin Feeling Abnormal Headache Nos Headache Nos Aggravated Hypertension Nos Lip Dry Tachycardia Nos Tongue Oedema Tremor Nec	Report Source	Product Accutane Loestrin Humulin Axid Propulsid Lotensin Norvasc	Company Report Numb	Role PS C C C C C C	Manufacturer	Route	
Outcome Other	Abdominal Pain Upper Anxiety Nec Breast Pain Diplopia Disorientation Dizziness (Exc Vertigo) Dry Skin Feeling Abnormal Headache Nos Headache Nos Aggravated Hypertension Nos Lip Dry Tachycardia Nos Tongue Cedema	Report Source Consumer	Product Accutane Loestrin Humulin Axid Propulsid Lotensin Norvasc Klonopin		Role PS C C C C C C C	Manufacturer	Route	
outcome Wher	PT Abdorninal Pain Upper Anxiety Nec Breast Pain Diplopia Disorientation Dizziness (Exc Vertigo) Dry Skin Feeding Abnormal Headache Nos Headache Nos Aggravated Hypertension Nos Lip Dry Tachycardia Nos Tongte Cedema Tremor Nec ISR Number: 3081442-6	Report Source Consumer Report Type: Expedited (Product Accutane Loestrin Humulin Axid Propulsid Lotensin Norvasc Klonopin	Company Report Number	Role PS C C C C C C C	Manufacturer	Route	
Dutcome ther te: 05/19/1998 J	PT Abdominal Pain Upper Anxiety Nee Breast Pain Diplopia Disorientation Dizziness (Exc Vertigo) Dry Skin Feeling Abnormal Headache Nos Headache Nos Aggravated Hypertension Nos Lip Dry Tachycardia Nos Tongue Oedema Tremor Nec ISR Number: 3081442-6 PT	Report Source Consumer	Product Accutane Loestrin Humulin Axid Propulsid Lotensin Norvasc Klonopin		Role PS C C C C C C C C		Route ORAL Age: 54 YR	Dose/Unit Duration Gender: Female
te: 05/19/1998 1	PT Abdominal Pain Upper Anxiety Nec Breast Pain Diplopia Disorientation Dizziness (Exc Vertigo) Dry Skin Feeling Abnormal Headache Nos Headache Nos Aggravated Hypertension Nos Lip Dry Tachycardia Nos Tongue Cedema Tremor Nec ISR Number: 3081442-6 PT Abdominal Pain Nos	Report Source Consumer Report Type: Expedited (Product Accutane Loestrin Humulin Axid Propulsid Lotensin Norvase Klonopin		Role PS C C C C C C C C C R R R R R R R R R R	Manufacturer	Route ORAL Age: 54 YR Route	Dose/Unit Duration
te: 05/19/1998	PT Abdominal Pain Upper Anxiety Nee Breast Pain Diplopia Disorientation Dizziness (Exc Vertigo) Dry Skin Feeling Abnormal Headache Nos Headache Nos Aggravated Hypertension Nos Lip Dry Tachycardia Nos Tongue Oedema Tremor Nec ISR Number: 3081442-6 PT	Report Source Consumer Report Type: Expedited (Report Source	Product Accutane Loestrin Humulin Axid Propulsid Lotensin Norvase Klonopin		Role PS C C C C C C C C		Route ORAL Age: 54 YR	Dose/Unit Duration Gender: Female

FDA - Adverse Event Reporting System (AERS Preedom Of Information (RCH) Report Date: 05/22/1998 ISR Number: 3081736-4 Report Type: Expedited (15-Day) Company Report Number: 99244 Age: 65 YR Gender: Male Outcome Report Source Product Role Hospitalization -Collapse Manufacturer Dose/Unit Duration Foreign Initial or Prolonged Tasmar PS Delusion Nos ORAL Other Sinemet Feeling Abnormal С Hypoglycaemia Nos Dothiepin С Parkinsonism Aggravated Bezalip-Mono C Aspirin С Date: 05/22/1998 ISR Number: 3081748-0 Report Type: Expedited (15-Day) Company Report Number: 96110 Age: 26 YR Gender: Female Outcome Report Source Product Role Manufacturer Depression Aggravated Dose/Unit Duration Hospitalization -Route Health Professional Initial or Prolonged Accutane PS Hyporeflexia ORAL Paxil Muscle Disorder Nos C Muscle Spasms Myalgia Neurological Disorder Nos Ovarian Disorder Nos Pain Nos Weight Increased Date: 05/22/1998 ISR Number: 3081750-9 Report Type: Expedited (15-Day) Company Report Number: 72202 Age: 24 YR Gender: Female . Outcome Report Source Product Role Disability Binocular Eye Movement Manufacturer Route Dose/Unit Duration Health Professional Accutane Disorder Nos PS ORAL Congenital Anomaly Blindness Transient Prozac С Blindness Unilateral Alcohol С Cerebral Palsy Complications Of Maternal Exposure To Therapuetic Drugs Congenital Central Nervous System Anomaly Nos Conjunctivitis Nec Convulsions Nos Developmental Coordination Disorder Nos Developmental Delay Nos Eye Discharge Eye Rolling Eyelid Malformation, Congenital Eyelid Ptosis Facial Dysmorphism

D. C. Connection		1114	Adve. Erector	e Event Report Of Informatio	litti Sy a (FO)	stem (AERS) Report		
Date: 06/02/1998	ISR Number: 3087606-X	Report Type: Expedite	ed (15-Day)	Company Report Num	han 00470			
Outcome	PT	_ Report Source	Product	y responentalli	IDEL: 334/6		Age: 16 YR	Gender: Male
Other	Depression Nec				Role	Manufacturer	Route	Dose/Unit Duration
1	Disturbance In Social Behavious Nos	•	Accutane		PS	**	ORAL	
	Influenza Like Illness							
·	Suicidal Ideation							
Date: 06/03/1998	ISR Number: 3088094-X	Report Type: Direct				· ·		
Outcome	PT	Report Type: Direct		Company Report Num	ber:		Age: 27 YR	Gender: Male
Death	Completed Suicide	Report Source	Product		Role	Monntostore		
	Depression Nec		Accutane		PS	Manufacturer	Route	Dose/Unit Duration
	Skin Disorder Nos				13			
Date: 06/03/1998	ISR Number: 3088115-4							
Outcome		Report Type: Direct		Company Report Numb	ber:		Age: 16 YR	
Life-Threatening	PT Alexander	Report Source	Product				Age: 16 YR	Gender: Male
Life-Tiffeatening	Abnormal Behaviour Nos Depression Nec		Accutane		Role	Manufacturer	Route	Dose/Unit Duration
	Mood Swings		· ····································		PS		ORAL	
	Suicidal Ideation							
Date: 06/02/1998	ISR Number: 3088349-9							
Outcome		Report Type: Expedited	(15-Day)	Company Report Numb	er: 95384		Age: 27 YR	
Death	_ <u>PT</u>	Report Source	Product				Age: 2/YR	Gender: Male
Deau Life-Threatening	Bipolar I Disorder Completed Suicide	Health Professional	Accutane		Role	Manufacturer	Route	Dose/Unit Duration
Life-Inreatening	Depression Nec	Other	1 toodtaig		PS		ORAL	
	Drug Abuse							
	Suicidal Ideation							
Oate: 06/02/1998	ISR Number: 3088662-5	Danast Town						
Outcome		Report Type: Direct		Company Report Number	er:		Age: 18 YR	C-1 - ·
Other	PT Crying	Report Source	Product		ъ.		10 1R	Gender: Female
	Depression Nec		Accutane		Role PS	Manufacturer	Route	Dose/Unit Duration
	Disturbance In Attention Nec				15			
ate: 06/04/1998	IOD N							
	•	Report Type: Expedited (15-Day)	Company Report Numbe	er: 99789		4	-
Outcome	PT	Report Source	Product				Age: 73 YR	Gender: Male
fospitalization - nitial or Prolonged	Drug Interaction Nos Psychotic Disorder Nos	Foreign	Tasmar		Role	Manufacturer	Route	Dose/Unit Duration
	1 Sychode Disorder Nos	Other	Sinemet	•	PS	**		

			Freedom	e Event Report Of Information		Report		
Date: 06/09/1998 Outcome	ISR Number: 3091174-6	Report Type: Expedit		Company Report Num			Age: 16 YR	
Other	PT PT	Report Source	Product			100	10 IK	Gender: Female
Oulei	Anorexia Anxiety Nec	Other	Accutane		Role	Manufacturer	Route	Dose/Unit Duration
	Depression Nec	. :			PS		ORAL	
	Fibromyalgia Syndrome							
	Gastrointestinal Candidiasis							
	Giardiasis							
	Myalgia							
	Sleep Disorder Nos							
	Swelling Nos							
-4 06.00.00.00	Weight Decreased							
ate: 06/09/1998	ISR Number: 3091176-X	Report Type: Expedite	1(15-Day)					
utcome	PT		- (10 Duy)	Company Report Numb	er: 99374		Age: 18 YR	Gender: Male
ospitalization -	Balance Impaired Nos	Report Source	Product		Role	Manufacturer	Dt.	_
itial or Prolonged	Diplopia	Foreign	Accutane		PS		Route	Dose/Unit Duration
	Electroencephalogram Normal	Health Professional					ORAL	
	Headache Nos							
	Hypertension Nos							
	Hypotension Loss Of Consciousness Nec							
	Stress Symptoms							
	Tremor Nec							
	Vision Blurred							
te: 06/08/1998	ISR Number: 3091562-8							
		Report Type: Expedited	(15-Day)	Company Report Number	r: SIN9800	50		
tcome	PT	Report Source	Product				Age: 72 YR	Gender: Male
spitalization - ial or Prolonged	Drug Interaction Nos	Foreign	Sinemet		Role	Manufacturer	Route	Dose/Unit Duration
	Psychotic Disorder Nos	Health Professional	Sinemet Cr		PS		ORAL	
	_				SS		ORAL	
e: 06/12/1998	ISR Number: 3091845-1		Tolcapone		SS			•
	2016 14 HILLION 1 309 1845-1	Report Type: Expedited	(15-Day)	Company Report Number	- 93367		 	
tcome	PT	Report Source	Product		22207		Age: 37 YR	Gender: Male
pitalization - al or Prolonged	Angina Pectoris	Foreign	-		Role	Manufacturer	Route	Dose/Unit Duration
uired Intervention	Angina Unstable	Health Professional	Soriatane		PS		ORAL	
revent Permanent	Anxiety Nec	Other	Roaccutane		SS		ORAL	
airment/Damage	Blood Triglycerides Increased Chest Pain		Tigason		SS		OKI IL	
	Coronary Artery Occlusion							

Data of Harris			reedom	Of Informati	on (EC)	tem (AERS) Repart		
Date: 06/10/1998	ISR Number: 3092459-X	Report Type: Expedited	l (15-Day)	Company Report N	mber: 98380		Age: 63 YR	0-1
Outcome	PT	Report Source	Product				.2ge. 05 1K	Gender: Male
Hospitalization - Initial or Prolonged	Disorientation	Health Professional	Tasmar		Role	Manufacturer	Route	Dose/Unit Duration
	Hepatic Encephalopathy		Sinemet		PS		ORAL	
	Hepatitis Nos Jaundice Nos				С			
	Liver Function Tests Nos		Vitamin E		C			
	Abnormal							
	Pyrexia							
	Tremor Nec							
	White Blood Cell Count Decreased							
ate: 06/10/1998	ISR Number: 3092796-9							
		Report Type: Direct		Company Report Nu	mber:		Age: 66 YR	Gender: Male
utcome	<u> PT</u>	Report Source	Product					Gender: Male
ospitalization - itial or Prolonged	Condition Aggravated		Tasmar		Role	Manufacturer	Route	Dose/Unit Duration
- Tanangea	Confusion Disorientation		Sinemet		PS		ORAL	
	Hallucinations Aggravated				С			
	Aggravated		Buspar		C			
			Klonopin		C			
			Colbenemid		C			
			Pepcid		С			
			Lasix		C			
			Accupril		C			•
			Eldepryl		C			
e: 06/16/1998			Zocor		С	·		
e: U0/16/1998	ISR Number: 3094924-8	Report Type: Expedited (15-Day)	Company Report Nu				
tcome	PT			Company Report Nu	nber: 95296		Age: 16 YR	Gender: Male
spitalization -	Depression Nec	Report Source	Product		Role	Manufacturer	Route	D
ial or Prolonged	Hallucination Nos	Other	Accutane	· -	PS		ORAL	Dose/Unit Duration
	Suicidal Ideation				*		OKAL,	
e: 06/16/1998	ISR Number: 3094927-3	Daniel T. V.						
tcome		Report Type: Expedited (15-Day)	Company Report Nur	nber: 97085		Age: 44 YR	Gender: Female
	PT	Report Source	Product					Gender: Female
er	Abdominal Distension	Consumer	Accutane		Role	Manufacturer	Route	Dose/Unit Duration
1	Blood Cholesterol Increased Blood Triglycerides Increased	Health Professional	. ICOURING		PS		ORAL	
	Depressed Mood							
	Fluid Retention							
	Headache Nos							

Date: 06/15/1998	18.		reedom	e Event Report Of Informatio	110 SQ 14000	ken (ALJES Report				
	ISR Number: 3095005-X	Report Type: Expedited	(15-Day)	Company Report Numl	ber: 89723		Age:		nder: Female	
Outcome	PT	Report Source	Product					Gen	nder: Pemale	
Disability	Abnormal Behaviour Nos	Health Professional			Role	Manufacturer	Route	Dose/Unit	Duration	
Congenital Anomaly	Attention Deficit/Hyperactivity Disorder Cardiac Disorder Nos	Other	Accutane		PS		ORAL			
	Clumsiness									
	Complications Of Maternal Exposure To Therapuetic Drugs Congenital Ventricular Septal									
	Defect Developmental Coordination Disorder Nos Developmental Delay Nos									
	Difficulty In Walking Disturbance In Attention Nec Hernia Nos									
	Hypospadias									
	Increased Activity									
	Learning Disorder Nos									
	Motor Dysfunction Nos									
	Urinary Incontinence									
	ISR Number: 3096777-0	Report Type: Expedited ((15-Day)	Company Report Numb	er: 100516		Age: 86 YR			
Outcome	PT	Report Source	Product				Age. 60 IK	Gen	der: Female	•
Other	Condition Aggravated	Health Professional			Role	Manufacturer	Route	Dose/Unit	Duration	
	Hallucination Nos		Tasmar		PS		ORAL			
	Visual Acuity Reduced	•								
	Visual Field Defect Nos									
Pate: 06/22/1998	SR Number: 3097269-5	Report Type: Expedited (15-Day)	Company Report Number	or 08380					
Outcome	PT	Report Source			va. 70500		Age: 63 YR	Gen	der: Male	
Iospitalization -	Biliary Tract Disorder Nos		Product		Role	Manufacturer	Route	Dose/Unit	Duration	
nitial or Prolonged	Cardiac Failure Congestive	Health Professional	Tasmar		PS		ORAL		25 47 411071	
	Coma Nec		Sinemet 25/2	50	С		OKAL,			
	Disorientation		Vitamin E		C					
	Gall Bladder Disorder Nos		Amantadine		c					
	Hepatic Cirrhosis Nos				C					
	Hepatic Encephalopathy									
	Hepatic Failure									
	Hepatitis Nos									
	Hyperpyrexia Infection Nos									

		1104		e Event Rep Of Informa	orling Sys	em (All RS)			
Date: 06/22/1998	ISR Number: 3097288-9	Report Type: Expedited				report			
Outcome	PT		(13-Day)	Company Report	Number: 100402		Age:	Gend	er: Female
Hospitalization -	Collanse	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	
Initial or Prolonged	Depression Nec	Foreign	Roaccutane	(Isotretinoin)	PS	-		Dose Ont	Duration
	Hypersensitivity Nos	Consumer	Antidepress	ant Nos	С				
	Neurodermatitis		Sedative N	os	С			•	
	Pyrexia				-				
	Suicidal Ideation	·							
Date: 06/23/1998	ISR Number: 3097844-8	Report Type: Expedited	(15-Day)	Company Report	Jumber: 100751		A 44 TIP		
Outcome	PT	Report Source	Product	•			Age: 14 YR	Gend	er: Female
Other	Confusion	Foreign			Role	Manufacturer	Route	Dose/Unit	Duration
	Crying	Health Professional	Roaccutane		PS		ORAL		
	Memory Impairment Repetitive Speech		Vallete		С				
)-t 060446									
late: 06/24/1998	ISR Number: 3098705-0	Report Type: Direct		C					
Outcome	PT			Company Report N	umber:		Age: 81 YR	Gende	er: Female
Other	Paranoia	Report Source	Product		Role	Manufacturer	Route	D # 14	
			Tasmar		PS			Dose/Unit	Duration
ate: 06/30/1998	ISR Number: 3100050-1	Down at Mr.					ORAL		
Outcome	•	Report Type: Expedited (15-Day)	Company Report N	umber: 101148		Age: 19 YR	C	
	PT	Report Source	Product				ge. 171K	Gende	er: Female .
ife-Threatening	Anxiety Nec	Health Professional	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
	Burning Sensation Nos Depression Nec				PS		ORAL		
	Depression Nec Dermatitis Nos		Depakote		C				
	Facial Palsy		Effexor		С				
	Goitre								
	Hypoaesthesia Tongue								
	Insomnia Nec								
	Neck Stiffness								
	Palpitations								
	Skin Discolouration	_							
	ISR Number: 3100112-9	Report Type: Expedited (1	5-Day)	Company Report No	mher: 97781	 			·
utcome	PT	Report Source	n				Age: 71 YR	Gende	r: Male
spitalization -	Confusion	Other	Product		Role	Manufacturer	Route	Dose/Unit	Duration
ial or Prolonged	Hyperglycaemia Nos		Tasmar		PS		ORAL		
	Sedation		Sinemet Cr		С				
	Urinary Incontinence		Glucophage		С				

FDA - Adverse Event Reporting System (AFRS Proedom Of Information (COI) Report Date: 06/30/1998 ISR Number: 3100307-4 Report Type: Expedited (15-Day) Company Report Number: 101424 Age: 19 YR Gender: Female Report Source Role Hospitalization -Initial or Prolonged Adjustment Disorder Nec Dose/Unit Duration Other Accutane PS Cellulitis ORAL Depression Nec Educational Problem Flat Affect Gender Identity Disorder Nos Loss Of Employment Scar Sedation Social Avoidant Behaviour Date: 07/02/1998 ISR Number: 3101702-X Report Type: Expedited (15-Day) Company Report Number: 93114 Age: 32 YR Gender: Female Outcome Report Source Product Abdominal Pain Nos Role Manufacturer Dose/Unit Duration Hospitalization -Consumer Accuatane Initial or Prolonged Bronchitis Nos PS ORAL Health Professional Complication Of Delivery Nos Complication Of Labour Nec Complications Of Maternal Exposure To Therapuetic Drugs Congenital Abnormality Nos Constipation Epiphyses Delayed Pusion Facial Dysmorphism Growth Retarded Hepatomegaly Hepatotoxicity Nos Herpes Zoster Hypermetropia Jaundice Neonatal Kidney Small Malaise Obstructed Labour Nos Otitis Media Nos Rhinitis Allergic Nos Stammering Date: 06/09/1998 ISR Number: 3101822-X Report Type: Periodic Company Report Number: 88381 Age: 32 YR Gender: Female Outcome Report Source Product Role Disturbance In Attention Nec Other Route Dose/Unit Duration Health Professional Accutane Capsules (Isotretinoin) PS Memory Impairment ORAL

Part	Date: 06/09/1998	ISR Number: 3101825-5	Report Type: Periodic		Company Report Nu	nber: 88388		Age: 38 YR		
Pajantations			Report Source	Product	· · · · · · · · · · · · · · · · · · ·					nuer: Pemale
Productons	Other		Consumer		Capsules (Isotretinoin)		Manufacturer		Dose/Unit	Duration
Outcome PT Roport Source Product Role Manufacture Role Manufacture Role Does / Los OEA Does / Los Does / Los </td <td>Date: 07/07/1998</td> <td>ISR Number: 3102757-9</td> <td>Report Type: Expedited (</td> <td>15-Day)</td> <td>Company Payard N</td> <td>101476</td> <td>· · · · · · · · · · · · · · · · · · ·</td> <td></td> <td></td> <td></td>	Date: 07/07/1998	ISR Number: 3102757-9	Report Type: Expedited (15-Day)	Company Payard N	101476	· · · · · · · · · · · · · · · · · · ·			
Hoginalization Ficial Bones Fracture Health Professional Accutane Role Role Manufacturer Role ORAL AL ORAL	Outcome	PT		•	Company Report Nu	aber: 1014/6		Age: 16 YR	Ger	nder: Male
Section Sect	Hospitalization -	Facial Bones Fracture				Role	Manufacturer	Route	Dose/Unit	Duration
Hydrochloride Road Traffic Accident Synocye Syn	Initial or Prolonged	Loss Of Consciousness Nec	ricami Professional			PS		ORAL		
Outcome F Report Source Product Report Source Product Role Manufacturer Role Manufacturer Role No munifacturer Ro		Road Traffic Accident				C				
PT	Date: 07/06/1998							-		
Product	Outcome	-		15-Day)	Company Report Nun	ber: 101338		Age: 64 YR	Ger	nder: Female
Ditted District				Product		Role	Manufacturer	Route	Dose/Unit	Duration
Markedly Reduced Food Intake Minapex C Minapex Minapex C Minapex Minapex C Minapex Minapex Minapex Minapex Minapex C Minapex			Other	Tasmar		PS				Dutation
				Sinemet (C	Carbidopa/Levodopa)	С				
Name Name		Weakness		Mirapex		С				
Name Control Name Control Name Company Report Number Company Rep		Weight Decreased		Hormone (Hormone Nos)	С				
Name Part Report Source Product Report Source Report Source Product Report Source				Xanax (Al	prazolam)	С				
PT Report Source Product Role Manufacturer Roule Dose/Unit Duration			Report Type: Direct		Company Report Nun	ber:		Age: 80 YR	Ger	ider Famela
Confusion Nos Sinemet Company Report Number: 96303 Age: 15 YR Gender: Male Outcome PT Report Source Product Oransinial or Prolonged Super Nos Super Su			Report Source	Product		ъ.		-		Temale
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