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4.a NAME AND	ADDRESS OF MANUF	ACTURER													
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23. OTHER RELE 23. OTHER RELE 24. ALLERGIC WHEAT - NOT CO 24. A NAME AND A Mirray Barnhi Stol-Myer Worldwide Sa Mail Location	VANT HISTORY(e.g.di TO GRASS*-NOT ODED #4 *ALLERGY ADDRESS OF MANUFA Ext Exquibb Compan fety & Surveill n HW19-1.01	agnostics, alle CODED #2 ° E POTATOES IV ACTURER	rgics,pregnar ALLERGY RI "-NOT CODI	AGWEED*	-NOT CO	DED #3	*ALLERG					
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AND URINALYS	TS, CREATINE PHOS IS WERE NEGATIVE.	FURTHER	e (CPK) Linfory	CREAT	inine, bl As been r	COD URI EQUESTI	ix niti id.	ROGI	236 (3	SUM)		I	T nee	:	
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PS URINALIST	s- MOINET	<u> </u>	<u> </u>		<u> </u>		4 2 5 2								
14.SUSPECT DRI	JG(S)(include generic na		SUSP	ECT DI	RUG(8)	INFOR	TAME	10	N			- 1			
	TABS 10 MG (prav		sodium)									A). DID RE	OPPING	DRUG?
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AT TO WITTING	z etn				#1 ORAL								□ vee	□no	□ne
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18. THERAPY DA				<u> </u>	19. THERA	PY DUR	LTION					٠,	1 yes	Ппо	Zina
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23. OTHER RELE	VANT HISTORY(e.g.diag	nostics,sile	rgics,prec	nancy with	last month o	of period.	etc.)						·		
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24.8 NAME AND A	ADDRESS OF MANUFAC	TURER													
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	fety & Surveillan	CO					İ								
P.O. Box 540 Princeton, N	J 08543-5400		1	R CONTRO											
United State		<u></u>	1,51,61	36918 PORT SOL											
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25. DATE OF THIS	REPORT	<u>romana na paris roman</u>	25e RE	PORT TYP	E						-	-			
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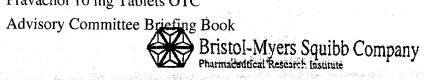




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1 Accidental overdose (therapeutic	c agent)								TIENT DI /OLVED (
A FEMALE CONSUMER REPORTED THAT SHE PABLETS (PRAVASTATIN SODIUM) 10 MG PABLETS (PRAVASTATIN SODIUM) 10 MG PABLE 10 MG DOSE OF LIPOSTAT THERAPY APRIL 27, 1995, SHE HAD TAREN AM AD PID MOT EXPERIENCE AN ADVERSE EVEN LAB DATA: \$1 NOT REPORTED	FOR HYPERCHOLES: THE NIGHT OF API DITTOMAL TABLET	PEROLEMIA. RIL 26, 19	THE PA	TIENT	MOI	TAKE			OLONGE PATIENT PSPITALIZ POLVED RSISTEN BABILITY CAPACITY	D ZATION CE OR T OR
								ТН	REATEN	NG
	II.SUSPECT D	RUG(S)	NFOF	MAT	TIO	N				
4.SUSPECT DRUG(S)(include generic name) 1 LIPOSTAT TABS 10 MG (pravastatin						-		20. DID R	EACTION TOPPING	ABATE DRUG?
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5.DOSE(S) 1 10 Milligram	•	16.ROUTE		NISTRA	HON			*:L2 ye	m L.,100	, TOT LIN
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17.INDICATION(S) FOR USE 11 Hypercholesterolaemia								21. DID R REAPPE REINTRO	AR AFTE	7
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	IV. MANUFAC	TURER	NFOR	MAT	101	4				
4.2 NAME AND ADDRESS OF MANUFACTURER								<u> </u>		
Murray Barnhart Bristol-Myers Squibb Company Worldwide Safety & Surveillance Mail Location HW19-1.01										
P.O. Box 5400 Princeton, NJ 08543-5400 United States	245 MFR CONTE B021414									
24c. DATE RECEIVED BY MANUFACTURER	24d REPORT SO		***************************************							
27APR1995	Study t	lterature ssional	Other							
25. DATE OF THIS REPORT	25e REPORT TY						•	•		
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			0,5	AUG	1995	ADVERS	E REACTIO	NC
*13 DESCRIBE REACTION(S)(Including relevant test abmormalities such as Bradycardia or while in the hospital, the patient was abmormalities present. Blood pressure is the old infarction and noted no pread the cold infarction and noted no pread the cold infarction and noted no pread the cold infarction and hotel no pread the cold infarction and suggest 9, 19 (Normal: 5 to 40 U/L) on august 9, 19 (Normal: 5 to 40 U/L) on august 9, 19 (Normal: 5 to 40 U/L) on august 9, 19 (Normal: 5 to 40 U/L) on august 9, 19 (Normal: 5 to 40 U/L) on august 9, 19 (Normal: 5 to 40 U/L) on august 9, 19 (Normal: 5 to 40 U/L) on august 9, 19 (Normal: 5 to 40 U/L) on august 9, 19 (Normal: 5 to 40 U/L) on august 9, 19 (Normal: 5 to 40 U/L) on august 9, 19 (Normal: 5 to 40 U/L) on august 9, 19 (Normal: 5 to 40 U/L) on august 9, 19 (Normal: 5 to 40 U/L) on august 9, 19 (Normal: 5 to 40 U/L) on august 9, 19 (Normal: 5 to 40 U/L) on august 9, 19 (Normal: 5 to 40 U/L) on august 9, 19 (Normal: 5 to 40 U/L) on august 9, 19 (Normal: 5 to 40 U/L) on august 9, 19 (Normal: 5 to 40 U/L) on august 9, 19 (Normal: 5 to 40 U/L) on august 9, 19 (Normal: 5 to 40 U/L) on august 9, 19 (Normal: 5 to 40 U/L) on august 9, 19 (Normal: 5 to 40 U/L) on august 9, 19 (Normal: 5 to 40 U/L) on august 9, 19 (Normal: 5 to 40 U/L) on august 9, 19 (Normal: 5 to 40 U/L) on august 9, 19 (Normal: 5 to 40 U/L) on august 9, 19 (Normal: 5 to 40 U/L) on august 9, 19 (Normal: 5 to 40 U/L) on august 9, 19 (Normal: 5 to 40 U/L) on august 9, 19 (Normal: 5 to 40 U/L) on august 9, 19 (Normal: 5 to 40 U/L) on august 9, 19 (Normal: 5 to 40 U/L) on august 9, 19 (Normal: 5 to 40 U/L) on august 9, 19 (Normal: 5 to 40 U/L) on august 9, 19 (Normal: 5 to 40 U/L) on august 9, 19 (Normal: 5 to 40 U/L) on august 9, 19 (Normal: 5 to 40 U/L) on august 9, 19 (Normal: 5 to 40 U/L) on august 9, 19 (Normal: 5 to 40 U/L) on august 9, 19 (Normal: 5 to 40 U/L) on august 9, 19 (Normal: 5 to 40 U/L) on august 9, 19 (Normal: 5 to 40 U/L) on august 9, 19 (Normal: 5 to 40 U/L) on august 9, 19 (Normal: 5 to 4	AV PROBLEMS. NO AS WELL AND THERE WAS 110/70 MMR PROLONGATION A FOR ALAMINE AMI 96, ALKALINE PHO 66 AND AUGUST 13 BOTH DISCONTINUE BATHER TO THE STI	E WERE NO CA 3. ELECTROCA NO SINUS BRA NOTRANSFERAS DSPHATASE 13 , 1996 RESPI ED. ACCORDINA TOTOR	RDIAC OR RDIOGRAM DYCARDIA E (ALAT) 6 U/L (NO CTIVELY. TO THE	PULMONAL SHOWED : WAS 55. 41 U/L RMAL: 30 PRAVASTI REPORTEI	RY SIGNS O TO ATIM	INVO PRO INVO PRO INVO PER SIGN DISA INC.	SISTENCE VIFICANT ABILITY OR APACITY	TIOI E OF
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3 ACETYLSALICYLIC ACID 4 ALCOHOL (ethyl alcohol)						AFTER ST	OPPING DI	RU
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#3 46		#3 ORAL						
#4		#4 ORAL		· · · · · · · · · · · · · · · · · · ·		#4 X yes	□no I	
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18. THERAPY DATES(frontio)		19. THERAPY D	URATION			- #3□ yes	□no	X
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22. CONCOMITANT DRUGS AND DATES OF ADMINIS	TRATION(exclude tho	se used to treat (eaction)					
23. OTHER RELEVANT HISTORY(e.g.diagnostics,alle	rgics,pregnancy with i	ast month of per	(od,etc.)					
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IV 24.8 NAME AND ADDRESS OF MANUFACTURER	. MANUFACT	URER INF	DRMATI	ON				
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	246 MFR CONTROL B028411	LNO						
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COLLOW-UP INFORMATION WAS RECE PATIENT EXPERIENCED A MYOCARDI CTOBER 30, 1995 AND DISCHARGE CODIUM THERAPY, 20 MG DAILY WA LEPORTED. PRAVASTATIN SODIUM T LAB DATA: \$1 CREATINE KINASE-0 2 U/L Normal, \$3 CREATINE KIN LIMASE-19AUG1996 90 U/L Normal LAT-09AUG1996 41 U/L Abnormal LAT-09AUG1996 41 U/L Abnormal LAT-09AUG1996 41 U/L Abnormal LAT-09AUG1996 41 U/L Normal, Continued)	AL INFARCTION AND WAS O IN MOVEMBER 1995. O S INITIATED AND NOT O HERAPY WAS INCREASED 9AUG1996 98 U/L NOTES ASE-13AUG1996 79 U/L , #5 CREATIME KINASE- , #7 ALAT-09AUG1996 3 37 U/L NOTES 1, #10 AL	ADMITTED N JANUARY N NOVEMBE TO 40 Mg 1, \$2 CRE NOTES1, \$ 20AUG1996 U/L NOTES AT-20AUG1	TO THE 11, 1: R 1, 1: DAILY (ATINE 1 4 CREAT 68 U/) mal, \$1 996 37	e hos 1995, 1995 al 1995 al 1905 al 1905 al 1905 al 1905 al 1905 al 1905 al 19	PITA PRAVE OR RCH E-09 mal, T-13	AUG	1996 1996	.Y .6.	8			INVERSE DISCUSSION LIFE	OLVEI DLONG ATIEN' SPITAL OLVEI SISTE NIFICA ABILIT APACI E	IZA NCI NCI NT YO	TIC E O	
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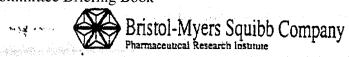
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Advisory Committee Briefing Book



Bristol-Myers Squibb Company
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Advisory Committee Briefing Book

Bristol-Myers Squibb Company
Pharmaceutical Research Institute

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7+13 DESCRIBE REACTION(S)(Including relevant	tests/iab data)			<u> </u>			PAT	TENT DIE	D
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IT WAS REPORTED THAT A 53-YEAR-OLD WHILE PARTICIPATING IN DOUBLE-BLIND RESTENOSIS WITH ELISOR (PRAVASTATIN PATIENT INITIATED PRAVASTATIN 20 MG MEDICATIONS INCLUDED SOTALOL, NITRI RAMIPRIL. IT WAS REPORTED THAT THE PERIOD OF FIFTY-ONE DAYS, (FROM FEB WAS REPORTED TO HAVE OCCURRED. THE DRUG THERAPY.	PHASE IV CLINIC () AFTER TRANSLOI DAILY OR PLACEI DERM, ACETYLSAL: PATIENT INGESTER PATIENT 1904 TO DELLEY 9 1004 TO	CAL TRIAL I CINAL CORON OO ON OCTOR CYLIC ACIE 144 TABLE	M THE LARY DI ER 8, TICL TS OF	PREVEN LATION. 1993. C OPIDINE STUDY D	TION OF THE ONCOMIT , AND RUG OVE	ant R a	PROSINE PROS	DLONGED ATIENT SPITALIZA DLVED ISISTENC NIFICANT ABILITY O APACITY	ATION E OR
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23. OTHER RELEVANT HISTORY(e.g.diagnostics,	illergics,pregnancy wit	h last month of	period,e	itc.)	 			 	·
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Princeton, NJ 08543-5400 United States	B019261								
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