



Report Title: **Statin Adverse Reactions in the CARM database**

Prepared for: **OIA Request – Heather Barker**

Prepared by: **New Zealand Pharmacovigilance Centre**

Period Covered: This search covers all spontaneous reports received by the Centre for Adverse Reactions Monitoring [CARM] from 01 January 2001 to 30 April 2021

Request Details: “...the number of adverse reactions to all brands of statins and cholesterol lowering medications including fatalities in the period 2001 to April 2021.”

“...breakdown of the type of adverse events.”

Summary: Statin medicines and cholesterol lowering medications reported 2001 to April 2021:

Atorvastatin	Bezafibrate
Fluvastatin	Ezetimibe
Pravastatin	Gemfibrozil
Rosuvastatin	
Simvastatin	

This document details 2235 reports describing 4997 reaction terms - one report may have more than one reaction described.

30 cases resulted in an outcome of death however in 3 cases death was not related to the Statin medicine and 7 cases were unclassifiable

Contents: Caveat Document
Reaction Listing



CAVEAT DOCUMENT

Accompanying statement to data released from the

NEW ZEALAND CENTRE FOR ADVERSE REACTIONS MONITORING

The Centre for Adverse Reactions Monitoring (CARM) has only limited details about each suspected adverse reaction contained in its Database. It is important that the limitations and qualifications which apply to the information and its use are understood.

The data made available represent the collection of spontaneous reports in the CARM database associated with therapeutic products/vaccines granted regulatory approval for use in New Zealand.

Reports have been submitted to the Centre since April 1965 and in many instances describe no more than suspicions which have arisen from observation of an unexpected or unwanted event. This level of reporting is due to CARM encouraging reporters to report events they suspect may be associated with a pharmaceutical product/vaccine irrespective of whether or not they believe it was the cause. CARM accepts all reports and proof of causality is not required when submitting a report to CARM. Coincidental events that may be unrelated to pharmaceutical product/vaccine exposure may be reported. This is particularly possible when the product has widespread use, or is used in targeted strategies such as vaccination campaigns.

In most instances it cannot be proven that a pharmaceutical product or ingredient is the cause of an event in the Database. Reports vary in quality, completeness and detail and may include detail that is incorrect. Consequently, a report in the CARM database of an event does not confirm that the pharmaceutical product/vaccine caused the event.

The volume of reports for a particular product may be influenced by the extent of use of the product, publicity, nature of reactions and other factors which vary over time and from product to product. It is generally accepted internationally that systems such as CARM are subject to underreporting which may result in scant reports for events perceived by the reporter to be minor or well recognised, whilst more serious or unexpected events are possibly more likely to be reported, even if they are coincidental. Moreover, no information is provided on the number of patients exposed to the product.

The data contained in these tables are further subject to ongoing internal quality controls, review and updating and therefore may be subject to change, particularly if follow-up information is received.

For the above reasons interpretations of adverse reaction data, and particularly those based on comparisons between pharmaceutical products, may be misleading. Any use of this information must take into account at least the above. Although this information is now released, it is strongly recommended that prior to any use of such information, CARM is contacted for interpretation.

Any publication, in whole or in part, of the obtained information must have published with it a statement:

- (i) of the source of the information
- (ii) that the information is not homogenous at least with respect to origin or likelihood that the pharmaceutical product/vaccine caused the adverse reaction
- (iii) that the information does not represent the opinion of the NZPhvC or CARM.

Director
New Zealand Pharmacovigilance Centre



Medicines:

In the period 01 January 2001 through to 30 April 2021 the following reports were received:

Atorvastatin	610	Bezafibrate	95
Fluvastatin	3	Ezetimibe	137
Pravastatin	27	Gemfibrozil	3
Rosuvastatin	31		
Simvastatin	1329		

Reports:

The breakdown per year was:

Year	Atorvastatin	Fluvastatin	Pravastatin	Rosuvastatin	Simvastatin	Bezafibrate	Ezetimibe	Gemfibrozil	Total
2001	25	3			13	14			55
2002	23				56	18		1	98
2003	9				73	9		1	92
2004	14				143	6	5		168
2005	9				166	7	25		207
2006	7				205	11	20		243
2007	18				103	2	21		144
2008	15				85	6	8		114
2009	20			2	190	6	6		224
2010	22				59	3	10		94
2011	46			4	33	2	8		93
2012	87		2	5	51	1	11		157
2013	63		6	3	37	4	4	1	118
2014	57		3	5	47	1	4		117
2015	37		3	5	22	2	8		77
2016	27		2	2	10	1	1		43
2017	48		1	1	3	1	1		55
2018	31		6	1	21		3		62
2019	27		1	2	6		2		38
2020	14		3	1	3				21
2021 April	11		0	0	3	1	0		15
Total	610	3	27	31	1329	95	137	3	2235



Fatalities:

Analysis of 30 cases resulting in death

Outcome	Atorvastatin	Rosuvastatin	Simvastatin	Total
Died due to the adverse reaction			8	8
Died medicine may be contributory	3	1	8	12
Died – cause unclassifiable	4	1	2	7
Died – unrelated to medicine	3			3

Reactions:

Details of the individual reaction terms and the number of times each term occurs are collated within clinical groupings in the following listing:

OIA - Cholesterol Lowering Medicines

RGROUP	reaction	Medicine								Total
		ATORVAS- TATIN	BEZAFIB- RATE	EZETIMI- BE	FLUVAST- ATIN	GEMFIBR- OZIL	PRAVAST- ATIN	ROSUVAS- TATIN	SIMVAST- ATIN	
		N	N	N	N	N	N	N	N	
Alimentary	ABDOMEN ENLARGED	1							1	2
	ABDOMINAL DISTENSION								3	3
	ABDOMINAL PAIN	20	2	11				1	50	84
	AGEUSIA								2	2
	ANOREXIA	3		4					4	11
	APPETITE DECREASED	2	1						1	4
	APPETITE INCREASED								1	1
	BLOATING	2							6	8
	BOWEL MOTILITY DISORDER								1	1
	BURNING SENSATION	1								1
	CHANGE IN BOWEL HABITS			3					2	5
	CHEILITIS								2	2
	CHOLECYSTITIS	1								1
	CHOLELITHIASIS	2	2						1	5
	COLIC ABDOMINAL			2					1	3
	COLITIS								1	1
	CONSTIPATION	6		3			1		22	32

(Continued)

OIA - Cholesterol Lowering Medicines

RGROUP	reaction	Medicine								Total
		ATORVAS- TATIN	BEZAFIB- RATE	EZETIMI- BE	FLUVAST- ATIN	GEMFIBR- OZIL	PRAVAST- ATIN	ROSUVAS- TATIN	SIMVAST- ATIN	
		N	N	N	N	N	N	N	N	
Alimentary	CRAMP ABDOMINAL	3	1				1		1	6
	DIARRHOEA	11	5	11				1	42	70
	DYSPEPSIA	4	3				1		22	30
	DYSPHAGIA	2	2						3	7
	ERUCTATION								5	5
	FAECAL INCONTINENCE			1					3	4
	FAECAL OCCULT BLOOD POSITIVE	1								1
	FAECES PALE	1								1
	FLATULENCE	4	1	3					17	25
	GASTRIC ULCER								2	2
	GASTRIC ULCER HAEMORRHAGIC								1	1
	GASTRITIS	1								1
	GASTRO-INTESTINAL DISORDER NOS	4								4
	GASTROENTERITIS								1	1
	GASTROESOPHAGEAL REFLUX	2		1					6	9
	GINGIVITIS	2								2
	GLOSSITIS	2								2

(Continued)

OIA - Cholesterol Lowering Medicines

RGROUP	reaction	Medicine								Total
		ATORVAS- TATIN	BEZAFIB- RATE	EZETIMI- BE	FLUVAST- ATIN	GEMFIBR- OZIL	PRAVAST- ATIN	ROSUVAS- TATIN	SIMVAST- ATIN	
		N	N	N	N	N	N	N	N	
Alimentary	HAEMORRHAGE RECTUM			1					1	2
	HAEMORRHOIDS								1	1
	HALITOSIS			1						1
	INCREASED STOOL FREQUENCY			1						1
	IRRITABLE BOWEL SYNDROME								1	1
	LIP DISORDER	1								1
	MELAENA	1								1
	MOUTH DRY	3	1						9	13
	MOUTH ULCERATION		1							1
	NAUSEA	25	6	8			2	2	63	106
	ORAL MUCOSA BLISTERING	1								1
	PANCREAS NEOPLASM MALIGNANT	1								1
	PROCTALGIA								2	2
	RECTAL BLEEDING	1							3	4
	RECTAL DISORDER	1								1
	STOMATITIS		1						3	4
	STOMATITIS ULCERATIVE								2	2

(Continued)

OIA - Cholesterol Lowering Medicines

RGROUP	reaction	Medicine								Total	
		ATORVAS- TATIN	BEZAFIB- RATE	EZETIMI- BE	FLUVAST- ATIN	GEMFIBR- OZIL	PRAVAST- ATIN	ROSUVAS- TATIN	SIMVAST- ATIN		
		N	N	N	N	N	N	N	N		
Alimentary	STOOLS ODOUR CHANGED	1								1	
	THROAT DRY								2	2	
	TONGUE DISCOLOURATION								1	1	
	TONGUE GEOGRAPHIC								1	1	
	TONGUE PAIN	1							3	4	
	TONGUE ULCERATION								1	1	
	TOOTH ABSCESS								1	1	
	TOOTH ACHE								2	2	
	TOOTH DISCOLOURATION								1	1	
	TOOTH DISORDER				1					1	
	VOMITING	4	2	2				1	23	32	
	*** Total for Group ***	115	28	53			5	5	321	527	
	Application Site	reaction									
		LIPODYSTROPHY							1		1
		*** Total for Group ***							1		1
Cardiovascular	reaction										
	ANGINA PECTORIS								1	1	

(Continued)

OIA - Cholesterol Lowering Medicines

RGROUP	reaction	Medicine								Total
		ATORVAS- TATIN	BEZAFIB- RATE	EZETIMI- BE	FLUVAST- ATIN	GEMFIBR- OZIL	PRAVAST- ATIN	ROSUVAS- TATIN	SIMVAST- ATIN	
		N	N	N	N	N	N	N	N	
Cardiovascular	ANGINA PECTORIS AGGRAVATED	2	1							3
	ARRHYTHMIA								2	2
	ATRIAL FIBRILLATION								2	2
	BRADYCARDIA	1							1	2
	CARDIAC ARREST	2							1	3
	CARDIAC FAILURE	1							4	5
	CARDIOMYOPATHY	1							1	2
	CARDIOVASCULAR DISORDERS								1	1
	CHEST DISCOMFORT	2								2
	CHEST PAIN	7		2				2	19	30
	CHEST TIGHTNESS	2		3					3	8
	COLLAPSE CIRCULATORY	1								1
	CONGESTIVE HEART FAILURE								1	1
	DIZZINESS	14	3	6			2	2	55	82
	ECG ABNORMAL	1								1
	FAINTNESS	1	1							2
	FLUSHING	1		1					5	7

(Continued)

OIA - Cholesterol Lowering Medicines

RGROUP	reaction	Medicine								Total
		ATORVAS- TATIN	BEZAFIB- RATE	EZETIMI- BE	FLUVAST- ATIN	GEMFIBR- OZIL	PRAVAST- ATIN	ROSUVAS- TATIN	SIMVAST- ATIN	
		N	N	N	N	N	N	N	N	
Cardiovascular	HEART DISORDER	1								1
	HYPERTENSION	2						1	5	8
	HYPERTENSION AGGRAVATED								2	2
	HYPOTENSION	3						1	5	9
	HYPOTENSION POSTURAL	2							1	3
	MYOCARDIAL INFARCTION	2		2				2		6
	MYOCARDITIS								1	1
	PALPITATION	5		4					11	20
	PERIPHERAL COLDNESS	1							1	2
	PERIPHERAL ISCHAEMIA	1	1							2
	PERIPHERAL VASOCONSTRICTION	1								1
	SYNCOPE	1	1	1					6	9
	TACHYCARDIA	1						1	1	3
	TACHYCARDIA VENTRICULAR	1								1
	THROMBOPHLEBITIS SUPERFICIAL								1	1
	THROMBOSIS ARTERIAL								1	1
	THROMBOSIS CORONARY							1		1

(Continued)

OIA - Cholesterol Lowering Medicines

	reaction	Medicine								Total
		ATORVAS- TATIN	BEZAFIB- RATE	EZETIMI- BE	FLUVAST- ATIN	GEMFIBR- OZIL	PRAVAST- ATIN	ROSUVAS- TATIN	SIMVAST- ATIN	
		N	N	N	N	N	N	N	N	
Cardiovascular	VASCULITIC RASH						1			1
	VASCULITIS								2	2
	VASOCONSTRICTION	1								1
	VASODILATION								1	1
	VEIN DISTENDED								1	1
	*** Total for Group ***	58	7	19			3	10	135	232
Collagen Disorders	reaction									
	ANTINUCLEAR FACTOR TEST POSITIVE	2							1	3
	*** Total for Group ***	2							1	3
Endocrine/Metabolic	reaction									
	AMYLASE INCREASED								3	3
	BLOOD TRIGLYCERIDES ABNORMAL		1							1
	BREAST ENLARGEMENT								1	1
	BREAST ENLARGEMENT MALE								2	2
	CREATINE PHOSPHOKINASE INCREASED	43	7	5				1	99	155
	CREATININE BLOOD INCREASED	1	3						3	7
	DEHYDRATION	1							1	2

(Continued)

OIA - Cholesterol Lowering Medicines

RGROUP	reaction	Medicine								Total
		ATORVAS- TATIN	BEZAFIB- RATE	EZETIMI- BE	FLUVAST- ATIN	GEMFIBR- OZIL	PRAVAST- ATIN	ROSUVAS- TATIN	SIMVAST- ATIN	
		N	N	N	N	N	N	N	N	
Endocrine/Metabolic	DIABETES MELLITUS	4		1					2	7
	DIABETES MELLITUS AGGRAVATED	4							1	5
	DIABETES MELLITUS NIDDM	2								2
	DIABETIC KETOACIDOSIS								1	1
	ELECTROLYTE ABNORMALITY	1								1
	FAT ATROPHY								2	2
	GOITRE	1								1
	GOUT		1						2	3
	GOUT AGGRAVATED								3	3
	GYNAECOMASTIA	6		1			1		6	14
	HDL DECREASED	1	4						1	6
	HYPERCHOLESTEROLAEMIA								1	1
	HYPERGLYCAEMIA	2		1					4	7
	HYPERKALAEMIA								3	3
	HYPERTRIGLYCERIDAEMIA	1								1
	HYPOGLYCAEMIA	1	1					1	2	5
	HYPOKALAEMIA								1	1

(Continued)

OIA - Cholesterol Lowering Medicines

RGROUP	reaction	Medicine								Total
		ATORVAS- TATIN	BEZAFIB- RATE	EZETIMI- BE	FLUVAST- ATIN	GEMFIBR- OZIL	PRAVAST- ATIN	ROSUVAS- TATIN	SIMVAST- ATIN	
		N	N	N	N	N	N	N	N	
Endocrine/Metabolic	HYPOMAGNEAEMIA								1	1
	LDH INCREASED								1	1
	LDL INCREASED		1							1
	MYOGLOBINURIA								1	1
	NPN INCREASED		1							1
	PANCREATITIS	4		3			1		11	19
	PEYRONIES DISEASE								1	1
	PLASMA OSMOLALITY INCREASED								1	1
	POLYDIPSIA								1	1
	SERUM FERRITIN INCREASED	1								1
	TESTOSTERONE DECREASED						1		1	2
	THIRST								2	2
	THYROID DISORDER								2	2
	TROPONIN T INCREASED								2	2
	WEIGHT DECREASE	8		1					7	16
	WEIGHT INCREASE	3		1					5	9
	*** Total for Group ***	84	19	13			3	2	174	295

(Continued)

OIA - Cholesterol Lowering Medicines

	reaction	Medicine								Total
		ATORVAS- TATIN	BEZAFIB- RATE	EZETIMI- BE	FLUVAST- ATIN	GEMFIBR- OZIL	PRAVAST- ATIN	ROSUVAS- TATIN	SIMVAST- ATIN	
		N	N	N	N	N	N	N	N	
RGROUP	reaction									
Foetal Disorders	FOETAL DISORDERS	1								1
	*** Total for Group ***	1								1
Haematological	reaction									
	ANAEMIA	5	5						3	13
	ANAEMIA APLASTIC								1	1
	ANAEMIA HAEMOLYTIC								1	1
	C-REACTIVE PROTEIN POSITIVE	2	1						6	9
	DISSEM. INTRAVASC. COAGULATION								1	1
	ECCHYMOSIS	1								1
	EOSINOPHILIA								1	1
	EPISTAXIS	3		1					7	11
	ESR INCREASED	1	1						1	3
	HAEMORRHAGE NOS	2								2
	INR DECREASED	1								1
	INR INCREASED	2							3	5
	LEUKOCYTOSIS								2	2
	LYMPHADENOPATHY								1	1

(Continued)

OIA - Cholesterol Lowering Medicines

RGROUP	reaction	Medicine								Total
		ATORVAS- TATIN	BEZAFIB- RATE	EZETIMI- BE	FLUVAST- ATIN	GEMFIBR- OZIL	PRAVAST- ATIN	ROSUVAS- TATIN	SIMVAST- ATIN	
		N	N	N	N	N	N	N	N	
Haematological	LYMPHOCYTOSIS	1								1
	NEUTROPENIA	1	1							2
	NEUTROPHILIA	1								1
	THROMBOCYTOPENIA	1	1	1	1			1		5
	THROMBOCYTOSIS								1	1
	*** Total for Group ***	21	9	2	1			1	28	62
Liver	BILIRUBINAEMIA	4							2	6
	BILIRUBINURIA	1								1
	GAMMA-GT INCREASED			1					1	2
	HEPATIC CIRRHOSIS								1	1
	HEPATIC CYST								1	1
	HEPATIC ENZYMES INCREASED	51	2	6		1			49	109
	HEPATIC FAILURE	1							5	6
	HEPATIC FUNCTION ABNORMAL	16	1	2					14	33
	HEPATIC NEOPLASM MALIGNANT	1								1
	HEPATITIS	9							5	14

(Continued)

OIA - Cholesterol Lowering Medicines

	reaction	Medicine								Total
		ATORVAS- TATIN	BEZAFIB- RATE	EZETIMI- BE	FLUVAST- ATIN	GEMFIBR- OZIL	PRAVAST- ATIN	ROSUVAS- TATIN	SIMVAST- ATIN	
		N	N	N	N	N	N	N	N	
RGROUP	reaction									
Liver	HEPATITIS CHOLESTATIC	6		1		1			4	12
	HEPATITIS VIRAL	1								1
	HEPATOCELLULAR DAMAGE	6							9	15
	HEPATOMEGALY	1				1			2	4
	HYPERBILIRUBINAEMIA	1							1	2
	JAUNDICE	5	1	2					10	18
	LIVER FATTY	1							1	2
	SGOT INCREASED								1	1
	*** Total for Group ***	104	4	12		3			106	229
Musculoskeletal	reaction									
	ARM PAIN	1							1	2
	ARTHRALGIA	29	2	7				1	85	124
	ARTHRITIS	2						3	7	12
	ARTHRITIS AGGRAVATED	2							1	3
	ARTHRITIS RHEUMATOID	1							2	3
	ARTHROPATHY	1							1	2
	BACK PAIN	9		5					31	45

(Continued)

OIA - Cholesterol Lowering Medicines

RGROUP	reaction	Medicine								Total
		ATORVAS- TATIN	BEZAFIB- RATE	EZETIMI- BE	FLUVAST- ATIN	GEMFIBR- OZIL	PRAVAST- ATIN	ROSUVAS- TATIN	SIMVAST- ATIN	
		N	N	N	N	N	N	N	N	
Musculoskeletal	BONE DISORDER								1	1
	BURSITIS	2								2
	CALF PAIN	1								1
	CRAMPS	12	3	2			1	1	31	50
	CRAMPS LEGS	1	2	3					11	17
	FASCITIS PLANTAR								1	1
	FRACTURE PATHOLOGICAL	1								1
	JAW PAIN	1							3	4
	JOINT EFFUSION								1	1
	JOINT PAIN	1		1			2		1	5
	JOINT STIFFNESS	2		2					3	7
	JOINT SWELLING NON-INFLAMMATORY	2					1		2	5
	LEG PAIN	5	1	3					14	23
	LUMBAR DISC LESION	1							1	2
	MOVEMENTS REDUCED							1	1	2
	MUSCLE ATROPHY	2								2
	MUSCLE PAIN	3							2	5

(Continued)

OIA - Cholesterol Lowering Medicines

RGROUP	reaction	Medicine								Total
		ATORVAS- TATIN	BEZAFIB- RATE	EZETIMI- BE	FLUVAST- ATIN	GEMFIBR- OZIL	PRAVAST- ATIN	ROSUVAS- TATIN	SIMVAST- ATIN	
		N	N	N	N	N	N	N	N	
Musculoskeletal	MUSCLE SPASTICITY		1						1	2
	MUSCLE STIFFNESS	5		1					5	11
	MUSCLE WASTING								4	4
	MUSCLE WEAKNESS	89	5	6			3	10	119	232
	MUSCULOSKELETAL DISORDER	1								1
	MUSCULOSKELETAL PAIN	2							2	4
	MYALGIA	124	17	28	1	1	3	7	325	506
	MYOPATHY	15	2	1					35	53
	MYOSITIS	13	2						20	35
	MYOSITIS NECROTISING	8								8
	NECK STIFFNESS	1								1
	PAIN IN LIMB								15	15
	PAIN NECK/SHOULDER	3		1					14	18
	POLYARTHRTIS		1							1
	POLYMYOSITIS	1							1	2
	RHABDOMYOLYSIS	17	2		1		1		55	76
	SKELETAL PAIN	2		1					13	16

(Continued)

OIA - Cholesterol Lowering Medicines

		Medicine								
		ATORVAS- TATIN	BEZAFIB- RATE	EZETIMI- BE	FLUVAST- ATIN	GEMFIBR- OZIL	PRAVAST- ATIN	ROSUVAS- TATIN	SIMVAST- ATIN	Total
		N	N	N	N	N	N	N	N	N
RGROUP	reaction									
Musculoskeletal	SYNOVITIS	1		1					4	6
	TENDINITIS	3		1					1	5
	TENDON DISORDER								2	2
	*** Total for Group ***	364	38	63	2	1	11	23	816	1318
Nervous System	reaction									
	ATAXIA	2							22	24
	BURNING SKIN						1			1
	CARPAL TUNNEL SYNDROME	1								1
	CEREBROVASCULAR DISORDER	1								1
	COGNITIVE FUNCTION ABNORMAL	2							1	3
	COMA			1						1
	CONVULSIONS								1	1
	CONVULSIONS AGGRAVATED	1								1
	COORDINATION ABNORMAL								2	2
	DROWSINESS								1	1
	DRUNKENNESS FEELING	1								1
	DYSAESTHESIA	9		2					16	27

(Continued)

OIA - Cholesterol Lowering Medicines

RGROUP	reaction	Medicine								Total
		ATORVAS- TATIN	BEZAFIB- RATE	EZETIMI- BE	FLUVAST- ATIN	GEMFIBR- OZIL	PRAVAST- ATIN	ROSUVAS- TATIN	SIMVAST- ATIN	
		N	N	N	N	N	N	N	N	
Nervous System	DYSKINESIA								1	1
	DYSPRAXIA	1								1
	ELECTRIC SHOCK SENSATION	1							1	2
	ENCEPHALOPATHY								1	1
	EXTRAPYRAMIDAL DISORDER								1	1
	FORMICATION	1						1	1	3
	FUZZY HEAD	1		1						2
	GAIT ABNORMAL	1					1			2
	HEADACHE	32	2	12			1	2	84	133
	HEADACHE VASOMOTOR								1	1
	HYPERAESTHESIA								1	1
	HYPERKINESIA		1						5	6
	HYPERTONIA	1		2					7	10
	HYPOAESTHESIA	2		1					13	16
	HYPOTONIA								1	1
	LIMB WEAKNESS								1	1
	MIGRAINE		1						4	5

(Continued)

OIA - Cholesterol Lowering Medicines

RGROUP	reaction	Medicine								Total
		ATORVAS- TATIN	BEZAFIB- RATE	EZETIMI- BE	FLUVAST- ATIN	GEMFIBR- OZIL	PRAVAST- ATIN	ROSUVAS- TATIN	SIMVAST- ATIN	
		N	N	N	N	N	N	N	N	
Nervous System	MOBILITY DECREASED	1							4	5
	MONONEURITIS								2	2
	MONOPLÉGIA	1								1
	MUSCLE CONTRACTIONS INVOLUNTARY	2							9	11
	MUSCLE FASCICULATION	1								1
	MYOCLONIC JERKS	1	1							2
	NERVE ROOT LESION								1	1
	NEURITIS SENSORY								1	1
	NEUROMYOPATHY								1	1
	NEUROPATHY								4	4
	NEUROPATHY PERIPHERAL	7		2					13	22
	NUMBNESS LOCALISED	2							5	7
	OCULOGYRIC CRISIS	1							1	2
	PAIN	4							6	10
	PAIN GROIN								1	1
	PAIN IN FACE								1	1
	PARAESTHESIA	4		1				2	1	37

(Continued)

OIA - Cholesterol Lowering Medicines

RGROUP	reaction	Medicine								Total
		ATORVAS- TATIN	BEZAFIB- RATE	EZETIMI- BE	FLUVAST- ATIN	GEMFIBR- OZIL	PRAVAST- ATIN	ROSUVAS- TATIN	SIMVAST- ATIN	
		N	N	N	N	N	N	N	N	
Nervous System	PARAESTHESIA DISTAL	9		1					7	17
	PARAESTHESIA LIPS	1								1
	PARAESTHESIA MOUTH								2	2
	PARAESTHESIA TONGUE								1	1
	PARALYSIS								1	1
	PERIPHERAL NEURITIS								1	1
	POLYNEUROPATHY	1								1
	RESTLESS LEGS						1		1	2
	SCIATICA			1						1
	SHAKING								2	2
	SPASM GENERALISED						1		1	2
	SPEECH DISORDER		1						1	2
	TRANSIENT ISCHAEMIC ATTACK								1	1
	TREMOR	3		1					4	8
	URINARY INCONTINENCE								1	1
	VERTIGO	4							7	11
	WEAKNESS GENERALIZED	1								1

(Continued)

OIA - Cholesterol Lowering Medicines

		Medicine								
		ATORVAS- TATIN	BEZAFIB- RATE	EZETIMI- BE	FLUVAST- ATIN	GEMFIBR- OZIL	PRAVAST- ATIN	ROSUVAS- TATIN	SIMVAST- ATIN	Total
		N	N	N	N	N	N	N	N	N
RGROUP	*** Total for Group ***									
Nervous System		100	6	25			7	4	281	423
Others	reaction									
	ACCIDENT	2						1	4	7
	ALCOHOL INTOLERANCE								1	1
	ALLERGIC REACTION	1							2	3
	ANAPHYLACTIC REACTION	1								1
	ANAPHYLACTOID REACTION	1								1
	BLOOD ALCOHOL EXCESSIVE								1	1
	BONE METASTASES	1								1
	CHILLS	1								1
	DRESS SYNDROME	2								2
	DRUG - ALCOHOL INTERACTION								1	1
	DRUG - FOOD INTERACTION	1							3	4
	DRUG INTERACTION	24	3						73	100
	FACE OEDEMA	2							6	8
	FALL	4							9	13
	FEELING COLD								2	2

(Continued)

OIA - Cholesterol Lowering Medicines

RGROUP	reaction	Medicine								Total
		ATORVAS- TATIN	BEZAFIB- RATE	EZETIMI- BE	FLUVAST- ATIN	GEMFIBR- OZIL	PRAVAST- ATIN	ROSUVAS- TATIN	SIMVAST- ATIN	
		N	N	N	N	N	N	N	N	
Others	FEELING OF WARMTH								3	3
	FEELING UNWELL								1	1
	FEVER	6		2					6	14
	HEAT INTOLERANCE		1							1
	HEAVINESS IN LIMBS	1								1
	HOT FLUSHES								1	1
	HYPOREFLEXIA	1								1
	INFLAMMATION			1						1
	INFLUENZA-LIKE SYMPTOMS	2		1				1	6	10
	LIPS SWELLING NON-SPECIFIC								2	2
	METASTASES NOS	2								2
	MULTIPLE ORGAN FAILURE	1							1	2
	NEOPLASM NOS		1							1
	NIGHT SWEATS	2		1					1	4
	NIPPLE PAIN	1								1
	OEDEMA		2						3	5
	OEDEMA LEGS	3		2					6	11

(Continued)

OIA - Cholesterol Lowering Medicines

RGROUP	reaction	Medicine								Total
		ATORVAS- TATIN	BEZAFIB- RATE	EZETIMI- BE	FLUVAST- ATIN	GEMFIBR- OZIL	PRAVAST- ATIN	ROSUVAS- TATIN	SIMVAST- ATIN	
		N	N	N	N	N	N	N	N	
Others	OEDEMA MOUTH	1							3	4
	OEDEMA PERIORBITAL	2							3	5
	OEDEMA PERIPHERAL	4	2						10	16
	PAIN TRAUMA ACTIVATED								1	1
	PALLOR								1	1
	POLYMYALGIA RHEUMATICA	1							1	2
	POLYMYALGIA RHEUMATICA AGGRAVATED	1								1
	PRIAPISM	1							1	2
	RIGORS		1						1	2
	SNORING								1	1
	SUDDEN DEATH	2							1	3
	SWEATING INCREASED		1						6	7
	TEMPERATURE CHANGED SENSATION	1	1						2	4
	THERAPEUTIC RESPONSE DECREASED								9	9
	THROAT SWELLING NON-SPECIFIC	1							3	4
	TONGUE OEDEMA	2							6	8
	TONGUE SWELLING NON-SPECIFIC	1							1	2

(Continued)

OIA - Cholesterol Lowering Medicines

	reaction	Medicine								Total
		ATORVAS- TATIN	BEZAFIB- RATE	EZETIMI- BE	FLUVAST- ATIN	GEMFIBR- OZIL	PRAVAST- ATIN	ROSUVAS- TATIN	SIMVAST- ATIN	
		N	N	N	N	N	N	N	N	
Others	UNEXPECTED THERAPEUTIC EFFECT								1	1
	*** Total for Group ***	76	12	7				2	183	280
Procedure Related	reaction									
	ACCIDENTAL OVERDOSE								1	1
	MEDICATION ERROR	2							21	23
	*** Total for Group ***	2							22	24
Product Related	reaction									
	BATCH DIFFERENCE	2								2
	BRAND SWITCH	63		6		1	2		157	229
	GENERIC SWITCH	10							10	20
	PACKAGING CHANGE		1							1
	PRODUCT FORMULATION CHANGE	13	1						1	15
	PRODUCT PROBLEM	1		2						3
	PRODUCT STORAGE ERROR	1								1
	*** Total for Group ***	90	2	8		1	2		168	271
Psychiatric Changes	reaction									
	AGGRESSIVE REACTION	3		2					4	9

(Continued)

OIA - Cholesterol Lowering Medicines

RGROUP	reaction	Medicine								Total
		ATORVAS- TATIN	BEZAFIB- RATE	EZETIMI- BE	FLUVAST- ATIN	GEMFIBR- OZIL	PRAVAST- ATIN	ROSUVAS- TATIN	SIMVAST- ATIN	
		N	N	N	N	N	N	N	N	
Psychiatric Changes	AGITATION								2	2
	AMNESIA	12		3					27	42
	ANGER								3	3
	ANXIETY	2					1		6	9
	ASTHENIA	1		2					12	15
	BEHAVIOUR ABNORMAL								1	1
	COGNITIVE DETERIORATION								2	2
	CONCENTRATION IMPAIRED	4	1				1	2	6	14
	CONFUSION	9		1					15	25
	DEMENTIA	1								1
	DEPERSONALIZATION	2						1	3	6
	DEPRESSION	14		2			3		32	51
	DEPRESSION AGGRAVATED	1								1
	DISORIENTATION	3	1						4	8
	DREAMING ABNORMAL	1	1					1	9	12
	EMOTIONAL LABILITY	2					2		4	8
	FATIGUE	26	3	3			2	1	32	67

(Continued)

OIA - Cholesterol Lowering Medicines

RGROUP	reaction	Medicine								Total
		ATORVAS- TATIN	BEZAFIB- RATE	EZETIMI- BE	FLUVAST- ATIN	GEMFIBR- OZIL	PRAVAST- ATIN	ROSUVAS- TATIN	SIMVAST- ATIN	
		N	N	N	N	N	N	N	N	
Psychiatric Changes	HALLUCINATION	2							6	8
	HALLUCINATION AUDITORY								1	1
	HALLUCINATION VISUAL	1		1						2
	INSOMNIA	14		3					16	33
	IRRITABILITY	1		2			1		3	7
	LETHARGY	14	1	7				1	43	66
	MALaise	9	1	2				2	18	32
	MEMORY DISTURBANCE	2					1			3
	MEMORY IMPAIRMENT	15	1	1			1		17	35
	MEMORY LOSS	15	1				1	1	13	31
	MOOD DISORDER	1		1					1	3
	MOOD SWINGS			1					1	2
	NERVOUSNESS		1						1	2
	PANIC REACTION								1	1
	PARANOID REACTION	1		1						2
	PARONIRIA	2	2	1			2		12	19
	PERSONALITY DISORDER								2	2

(Continued)

OIA - Cholesterol Lowering Medicines

	reaction	Medicine								Total
		ATORVAS- TATIN	BEZAFIB- RATE	EZETIMI- BE	FLUVAST- ATIN	GEMFIBR- OZIL	PRAVAST- ATIN	ROSUVAS- TATIN	SIMVAST- ATIN	
		N	N	N	N	N	N	N	N	
Psychiatric Changes	SLEEP DISORDER	1						1	2	4
	SLEEP DISTURBED	2		2					8	12
	SLEEP RESTLESS						1			1
	SOMNAMBULISM								1	1
	SOMNOLENCE	2		2					8	12
	SUICIDAL IDEATION	1					1			2
	SUICIDAL TENDENCY								4	4
	SUICIDE								1	1
	SUICIDE ATTEMPT								1	1
	TEARFUL	2								2
	THINKING ABNORMAL								4	4
	TIREDNESS	7		1					22	30
	*** Total for Group ***	173	13	38			17	10	348	599
Reproductive Disorders	BREAST PAIN								1	1
	BREAST PAIN FEMALE	1							1	2
	BREAST PAIN MALE								4	4

(Continued)

OIA - Cholesterol Lowering Medicines

RGROUP	reaction	Medicine								Total
		ATORVAS- TATIN	BEZAFIB- RATE	EZETIMI- BE	FLUVAST- ATIN	GEMFIBR- OZIL	PRAVAST- ATIN	ROSUVAS- TATIN	SIMVAST- ATIN	
		N	N	N	N	N	N	N	N	
Reproductive Disorders	BREAST TENDERNESS	1								1
	EJACULATION DELAYED		1							1
	ERECTILE DYSFUNCTION	1							2	3
	GENITAL ULCERATION								1	1
	IMPOTENCE	2	1						7	10
	LIBIDO DECREASED	2							3	5
	LIBIDO INCREASED			1						1
	*** Total for Group ***	7	2	1					19	29
Resistance Mechanism Disorders	reaction									
	ABSCESS								1	1
	ANTIBODIES DRUG SPECIFIC	11							2	13
	CANDIDIASIS	1								1
	CELLULITIS	1								1
	SEPSIS								1	1
	*** Total for Group ***	13							4	17
Respiratory	reaction									
	BRONCHITIS								1	1

(Continued)

OIA - Cholesterol Lowering Medicines

RGROUP	reaction	Medicine								Total
		ATORVAS- TATIN	BEZAFIB- RATE	EZETIMI- BE	FLUVAST- ATIN	GEMFIBR- OZIL	PRAVAST- ATIN	ROSUVAS- TATIN	SIMVAST- ATIN	
		N	N	N	N	N	N	N	N	
Respiratory	BRONCHOSPASM		1						1	2
	BRONCHOSPASM AGGRAVATED	2		1						3
	CORYZA								1	1
	COUGHING	4	1	3			1		14	23
	DYSPNOEA	10	1	1			2		32	46
	HOARSENESS	1								1
	INTERSTITIAL LUNG DISEASE	1						1	1	3
	LOWER RESP TRACT INFECTION	1								1
	NASAL CONGESTION	2	1							3
	NASAL DRYNESS								1	1
	PHARYNGITIS	1					1		1	3
	PNEUMONIA	1		1					3	5
	PNEUMONIA INTERSTITIAL								1	1
	PNEUMONITIS	1								1
	PULMONARY DISORDERS								1	1
	PULMONARY FIBROSIS	1							1	2
	PULMONARY OEDEMA								1	1

(Continued)

OIA - Cholesterol Lowering Medicines

RGROUP	reaction	Medicine								Total
		ATORVAS- TATIN	BEZAFIB- RATE	EZETIMI- BE	FLUVAST- ATIN	GEMFIBR- OZIL	PRAVAST- ATIN	ROSUVAS- TATIN	SIMVAST- ATIN	
		N	N	N	N	N	N	N	N	
Respiratory	RESPIRATORY DISORDER								1	1
	RESPIRATORY FAILURE								1	1
	RHINITIS	2							2	4
	SINUSITIS	1							1	2
	SNEEZING EXCESSIVE	1								1
	SPUTUM INCREASED			1						1
	THROAT IRRITATION	1							1	2
	THROAT TIGHTNESS			1					6	7
	*** Total for Group ***	30	4	8			4	1	71	118
Skin and Appendages	reaction									
	ALOPECIA	6	9	1					35	51
	ALOPECIA AREATA	1							1	2
	ANGIOEDEMA	4	1	1			2		8	16
	BLISTERS	1								1
	BULLOUS ERUPTION	2	2						4	8
	DERMATITIS	2							2	4
	DERMATITIS EXFOLIATIVE								1	1

(Continued)

OIA - Cholesterol Lowering Medicines

RGROUP	reaction	Medicine								Total
		ATORVAS- TATIN	BEZAFIB- RATE	EZETIMI- BE	FLUVAST- ATIN	GEMFIBR- OZIL	PRAVAST- ATIN	ROSUVAS- TATIN	SIMVAST- ATIN	
		N	N	N	N	N	N	N	N	
Skin and Appendages	DERMATITIS LICHENOID	1								1
	DERMOGRAPHIA	1								1
	ECZEMA	2		1					3	6
	ERYTHEMA	3						1		4
	ERYTHEMA MULTIFORME	1							2	3
	ERYTHRODERMA	1								1
	HAIR DISORDER NOS								1	1
	HAIR LOSS	4	1					1	4	10
	HAIR TEXTURE ABNORMAL	1							1	2
	HAIR THINNING							1		1
	HERPES SIMPLEX	1								1
	LE SYNDROME	1							1	2
	LUPUS ERYTHEMATOSUS SYSTEMIC	1								1
	MACULAR RASH	1		1						2
	MELANOMA MALIGNANT	2								2
	MORBILLIFORM RASH			1						1
	NAIL DISORDER								1	1

(Continued)

OIA - Cholesterol Lowering Medicines

RGROUP	reaction	Medicine								Total
		ATORVAS- TATIN	BEZAFIB- RATE	EZETIMI- BE	FLUVAST- ATIN	GEMFIBR- OZIL	PRAVAST- ATIN	ROSUVAS- TATIN	SIMVAST- ATIN	
		N	N	N	N	N	N	N	N	
Skin and Appendages	PEMPHIGOID REACTION								1	1
	PHOTOSENSITIVITY REACTION	3	4	1				1	7	16
	PRURITUS	14	1						29	44
	PRURITUS ANI	1								1
	PSORIASIS AGGRAVATED								1	1
	PURPURA	1	1	1					5	8
	RASH	18	4	3				1	28	54
	RASH ERYTHEMATOUS	5		3					7	15
	RASH MACULO-PAPULAR	2							2	4
	RASH PETECHIAL								1	1
	RASH PRURITIC	9	3	1					25	38
	RASH PURPURIC								1	1
	RASH PUSTULAR								2	2
	SCAR								1	1
	SKIN DISCOLOURATION	1							1	2
	SKIN DISORDER	1								1
	SKIN DRY	1		1						2

(Continued)

OIA - Cholesterol Lowering Medicines

RGROUP	reaction	Medicine								Total
		ATORVAS- TATIN	BEZAFIB- RATE	EZETIMI- BE	FLUVAST- ATIN	GEMFIBR- OZIL	PRAVAST- ATIN	ROSUVAS- TATIN	SIMVAST- ATIN	
		N	N	N	N	N	N	N	N	
Skin and Appendages	SKIN EXFOLIATION								2	2
	SKIN IRRITATION	1							1	2
	SKIN NODULE								1	1
	SKIN ODOUR ABNORMAL	1								1
	SKIN ULCERATION								1	1
	TOXIC EPIDERMAL NECROLYSIS	1								1
	URTICARIA	11		1				2	20	34
	VESICULAR RASH			1					1	2
	*** Total for Group ***	106	27	16			3	6	201	359
	Special Senses	ANOSMIA	1		1					4
CATARACT									1	1
CHROMATOPSIA		1								1
CONJUNCTIVITIS		2							4	6
DIPLOPIA									4	4
DRY EYES									1	1
DYSGEUSIA		2							3	5

(Continued)

OIA - Cholesterol Lowering Medicines

		Medicine								
		ATORVAS-	BEZAFIB-	EZETIMI-	FLUVAST-	GEMFIBR-	PRAVAST-	ROSUVAS-	SIMVAST-	Total
		TATIN	RATE	BE	ATIN	OZIL	ATIN	TATIN	ATIN	N
		N	N	N	N	N	N	N	N	N
RGROUP	reaction									
Special Senses	EYE PAIN								1	1
	GLAUCOMA								1	1
	HEARING IMPAIRED								1	1
	KERATOCONJUNCTIVITIS								1	1
	LACRIMATION ABNORMAL	1							3	4
	OCULAR HAEMORRHAGE								1	1
	PAROSMIA						1		1	2
	PHOTOPHOBIA	1								1
	TASTE BITTER	1							1	2
	TASTE LOSS	2		1					1	4
	TASTE METALLIC	1							4	5
	TASTE PERVERSION	3					1		3	7
	TINNITUS	1					1	1	4	7
	TINNITUS AGGRAVATED								1	1
	UVEITIS								1	1
	VISION ABNORMAL		2						8	10
	VISION BLURRED	1		3			1		9	14

(Continued)

OIA - Cholesterol Lowering Medicines

		Medicine								
		ATORVAS- TATIN	BEZAFIB- RATE	EZETIMI- BE	FLUVAST- ATIN	GEMFIBR- OZIL	PRAVAST- ATIN	ROSUVAS- TATIN	SIMVAST- ATIN	Total
		N	N	N	N	N	N	N	N	N
RGROUP	reaction									
Special Senses	VISION DECREASED	1								1
	XEROPHTHALMIA								3	3
	*** Total for Group ***	18	2	5			4	1	61	91
Urinary	reaction									
	ANURIA								1	1
	CREATININE CLEARANCE DECREASED		3							3
	DYSURIA						1		1	2
	ENURESIS								1	1
	HAEMATURIA								5	5
	HYDRONEPHROSIS	1								1
	KIDNEY CONTRACTED								1	1
	MICTURITION DISORDER		1						2	3
	MICTURITION FREQUENCY	2	1	1			2		4	10
	NEPHRITIS INTERSTITIAL	1						1		2
	NOCTURIA	2							2	4
	NOCTURIA AGGRAVATED								1	1
	OLIGURIA								2	2

(Continued)

OIA - Cholesterol Lowering Medicines

RGROUP	reaction	Medicine								Total
		ATORVAS- TATIN	BEZAFIB- RATE	EZETIMI- BE	FLUVAST- ATIN	GEMFIBR- OZIL	PRAVAST- ATIN	ROSUVAS- TATIN	SIMVAST- ATIN	
		N	N	N	N	N	N	N	N	
Urinary	POLYURIA	2								2
	PROSTATIC DISORDER		1							1
	RENAL FAILURE ACUTE	4	2					1	30	37
	RENAL FAILURE AGGRAVATED		3						3	6
	RENAL FAILURE CHRONIC AGGRAVATED		1							1
	RENAL FAILURE NOS								3	3
	RENAL FUNCTION ABNORMAL	1	3						4	8
	RENAL IMPAIRMENT	5								5
	RENAL PAIN								3	3
	RENAL TUBULAR NECROSIS	1								1
	RETROPERITONEAL FIBROSIS	1								1
	URINE ABNORMAL								3	3
	URINE DISCOLOURATION	5							1	6
	URINE FLOW DECREASED	1						1		2
	URINE ODOUR FOUL	1		1					1	3
	*** Total for Group ***	27	15	2	3	5	3	3	68	118
Total Reactions		1391	188	272	3	5	62	69	3007	4997