



New Zealand Pharmacovigilance Centre

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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 2018

Request Details: “...the number of adverse reactions to all brands of statins and cholesterol lowering medications including fatalities in the period 2001 to April 2018.”

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

Summary: Statin medicines and cholesterol lowering medications reported 2001 to April 2018:

Atorvastatin	Bezafibrate
Fluvastatin	Ezetimibe
Pravastatin	Gemfibrozil
Rosuvastatin	
Simvastatin	

This document details 2115 reports describing 4720 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 2018 the following reports were received:

Atorvastatin	537	Bezafibrate	94
Fluvastatin	3	Ezetimibe	132
Pravastatin	18	Gemfibrozil	3
Rosuvastatin	27		
Simvastatin	1301		

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 April	10		1		5	0	0		16
Total	537	3	18	27	1301	94	132	3	2115



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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-	BEZAFIB-	EZETIMI-	FLUVAST-	GEMFIBR-	PRAVAST-	ROSUVAS-	SIMVAST-	
		TATIN	RATE	BE	ATIN	OZIL	ATIN	TATIN	ATIN	
		N	N	N	N	N	N	N	N	
Alimentary	ABDOMEN ENLARGED	1							1	2
	ABDOMINAL DISTENSION								3	3
	ABDOMINAL PAIN	18	2	11				1	50	82
	AGEUSIA								2	2
	ANOREXIA	2		4					4	10
	APPETITE DECREASED		1						1	2
	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

OIA - Cholesterol Lowering Medicines

RGROUP	reaction	Medicine								Total
		ATORVAS-	BEZAFIB-	EZETIMI-	FLUVAST-	GEMFIBR-	PRAVAST-	ROSUVAS-	SIMVAST-	
		TATIN	RATE	BE	ATIN	OZIL	ATIN	TATIN	ATIN	
		N	N	N	N	N	N	N	N	
Alimentary	CRAMP ABDOMINAL	2	1					1	4	
	DIARRHOEA	10	5	11			1	41	68	
	DYSPEPSIA	2	3				1	22	28	
	DYSPHAGIA	2	2					3	7	
	ERUCTATION							4	4	
	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	
	GASTRO- INTESTINAL DISORDER NOS	4							4	
	GASTROENTERITIS							1	1	
	GASTROESOPHAGEAL REFLUX	2		1				5	8	
	GINGIVITIS	2							2	
	GLOSSITIS	2							2	
	HAEMORRHAGE RECTUM			1				1	2	

OIA - Cholesterol Lowering Medicines

RGROUP	reaction	Medicine								Total
		ATORVAS-	BEZAFIB-	EZETIMI-	FLUVAST-	GEMFIBR-	PRAVAST-	ROSUVAS-	SIMVAST-	
		TATIN	RATE	BE	ATIN	OZIL	ATIN	TATIN	ATIN	
		N	N	N	N	N	N	N	N	
Alimentary	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						7	11
	MOUTH ULCERATION		1							1
	NAUSEA	21	6	8			1	1	62	99
	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
	STOOLS ODOUR CHANGED	1								1

OIA - Cholesterol Lowering Medicines

RGROUP	reaction	Medicine								Total	
		ATORVAS-	BEZAFIB-	EZETIMI-	FLUVAST-	GEMFIBR-	PRAVAST-	ROSUVAS-	SIMVAST-		
		TATIN	RATE	BE	ATIN	OZIL	ATIN	TATIN	ATIN		
		N	N	N	N	N	N	N	N		
Alimentary	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 ***	101	28	53				3	4	315	504
	Application Site	reaction									
		LIPODYSTROPHY								1	1
*** Total for Group ***									1	1	
Cardiovascular	reaction										
	ANGINA PECTORIS								1	1	
	ANGINA PECTORIS AGGRAVATED	2	1							3	

OIA - Cholesterol Lowering Medicines

RGROUP	reaction	Medicine								Total
		ATORVAS-	BEZAFIB-	EZETIMI-	FLUVAST-	GEMFIBR-	PRAVAST-	ROSUVAS-	SIMVAST-	
		TATIN	RATE	BE	ATIN	OZIL	ATIN	TATIN	ATIN	
		N	N	N	N	N	N	N	N	
Cardiovascular	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				1	19	29
	CHEST TIGHTNESS	2		3					3	8
	COLLAPSE CIRCULATORY	1								1
	CONGESTIVE HEART FAILURE								1	1
	DIZZINESS	11	3	6			2	2	54	78
	ECG ABNORMAL	1								1
	FAINTNESS	1	1							2
	FLUSHING	1		1					5	7
	HEART DISORDER	1								1

OIA - Cholesterol Lowering Medicines

RGROUP	reaction	Medicine								Total
		ATORVAS-	BEZAFIB-	EZETIMI-	FLUVAST-	GEMFIBR-	PRAVAST-	ROSUVAS-	SIMVAST-	
		TATIN	RATE	BE	ATIN	OZIL	ATIN	TATIN	ATIN	
		N	N	N	N	N	N	N	N	
Cardiovascular	HYPERTENSION	2							5	7
	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
	PERIPHERAL ISCHAEMIA	1	1							2
	PERIPHERAL VASOCONSTRICTION	1								1
	SYNCOPE	1	1	1					6	9
	TACHYCARDIA	1							1	2
	TACHYCARDIA VENTRICULAR	1								1
	THROMBOPHLEBITIS SUPERFICIAL								1	1
	THROMBOSIS ARTERIAL								1	1
	THROMBOSIS CORONARY							1		1
	VASCULITIS								2	2

OIA - Cholesterol Lowering Medicines

RGROUP	reaction	Medicine								Total
		ATORVAS-	BEZAFIB-	EZETIMI-	FLUVAST-	GEMFIBR-	PRAVAST-	ROSUVAS-	SIMVAST-	
		TATIN	RATE	BE	ATIN	OZIL	ATIN	TATIN	ATIN	
		N	N	N	N	N	N	N	N	
Cardiovascular	VASOCONSTRICTION	1								1
	VASODILATION								1	1
	VEIN DISTENDED								1	1
	*** Total for Group ***	55	7	19			2	7	133	223
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	38	7	5				1	97	148
	CREATININE BLOOD INCREASED	1	3						3	7
	DEHYDRATION	1							1	2
	DIABETES MELLITUS	4		1					2	7
	DIABETES MELLITUS AGGRAVATED	4							1	5

OIA - Cholesterol Lowering Medicines

RGROUP	reaction	Medicine								Total
		ATORVAS-	BEZAFIB-	EZETIMI-	FLUVAST-	GEMFIBR-	PRAVAST-	ROSUVAS-	SIMVAST-	
		TATIN	RATE	BE	ATIN	OZIL	ATIN	TATIN	ATIN	
		N	N	N	N	N	N	N	N	
Endocrine/Metabolic	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	3					1		6	10
	HDL DECREASED	1	4						1	6
	HYPERCHOLESTEROLAEMIA								1	1
	HYPERGLYCAEMIA	1		1					4	6
	HYPERKALAEMIA								3	3
	HYPERTRIGLYCERIDAEMIA	1								1
	HYPOGLYCAEMIA	1	1					1	2	5
	HYPOKALAEMIA								1	1
	HYPOMAGNESAEMIA								1	1
	LDH INCREASED								1	1

OIA - Cholesterol Lowering Medicines

RGROUP	reaction	Medicine								Total
		ATORVAS-	BEZAFIB-	EZETIMI-	FLUVAST-	GEMFIBR-	PRAVAST-	ROSUVAS-	SIMVAST-	
		TATIN	RATE	BE	ATIN	OZIL	ATIN	TATIN	ATIN	
		N	N	N	N	N	N	N	N	
Endocrine/Metabolic	LDL INCREASED		1							1
	MYOGLOBINURIA								1	1
	NPN INCREASED		1							1
	PANCREATITIS	3		3					11	17
	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	5		1					7	13
	WEIGHT INCREASE	2		1					5	8
	*** Total for Group ***	70	19	12			2	2	172	277
Foetal Disorders	reaction									
	FOETAL DISORDERS	1								1

OIA - Cholesterol Lowering Medicines

RGROUP	*** Total for Group ***	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	
Foetal Disorders		1								1
Haematological	reaction									
	ANAEMIA	5	5						3	13
	ANAEMIA APLASTIC								1	1
	ANAEMIA HAEMOLYTIC								1	1
	C-REACTIVE PROTEIN POSITIVE	2	1						5	8
	DISSEM. INTRAVASC. COAGULATION								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
	LYMPHOCYTOSIS	1								1
	NEUTROPENIA		1							1

OIA - Cholesterol Lowering Medicines

RGROUP	reaction	Medicine								Total
		ATORVAS-	BEZAFIB-	EZETIMI-	FLUVAST-	GEMFIBR-	PRAVAST-	ROSUVAS-	SIMVAST-	
		TATIN	RATE	BE	ATIN	OZIL	ATIN	TATIN	ATIN	
		N	N	N	N	N	N	N	N	
Haematological	THROMBOCYTOPENIA	1	1	1	1			1		5
	THROMBOCYTOSIS								1	1
	*** Total for Group ***	18	9	2	1			1	27	58
Liver	BILIRUBINAEMIA	2							1	3
	BILIRUBINURIA	1								1
	GAMMA-GT INCREASED			1					1	2
	HEPATIC CIRRHOSIS								1	1
	HEPATIC CYST								1	1
	HEPATIC ENZYMES INCREASED	44	2	6		1			48	101
	HEPATIC FAILURE								5	5
	HEPATIC FUNCTION ABNORMAL	13	1	1					14	29
	HEPATIC NEOPLASM MALIGNANT	1								1
	HEPATITIS	4							5	9
	HEPATITIS CHOLESTATIC	5		1		1			4	11
	HEPATITIS VIRAL	1								1
	HEPATOCELLULAR DAMAGE	3							8	11

OIA - Cholesterol Lowering Medicines

RGROUP	reaction	Medicine								Total	
		ATORVAS-	BEZAFIB-	EZETIMI-	FLUVAST-	GEMFIBR-	PRAVAST-	ROSUVAS-	SIMVAST-		
		TATIN	RATE	BE	ATIN	OZIL	ATIN	TATIN	ATIN		
		N	N	N	N	N	N	N	N		
Liver	HEPATOMEGALY	1				1			2	4	
	HYPERBILIRUBINAEMIA								1	1	
	JAUNDICE	3	1	2					10	16	
	LIVER FATTY	1							1	2	
	SGOT INCREASED								1	1	
	*** Total for Group ***	79	4	11		3			103	200	
	Musculoskeletal	ARTHRALGIA	29	2	7				1	82	121
		ARTHRITIS	2						3	7	12
ARTHRITIS AGGRAVATED		2								2	
ARTHRITIS RHEUMATOID		1							2	3	
ARTHROPATHY		1							1	2	
BACK PAIN		8		4					31	43	
BONE DISORDER									1	1	
BURSITIS		2								2	
CALF PAIN		1								1	
CRAMPS		11	3	2				1	31	48	

OIA - Cholesterol Lowering Medicines

RGROUP	reaction	Medicine								Total
		ATORVAS-	BEZAFIB-	EZETIMI-	FLUVAST-	GEMFIBR-	PRAVAST-	ROSUVAS-	SIMVAST-	
		TATIN	RATE	BE	ATIN	OZIL	ATIN	TATIN	ATIN	
		N	N	N	N	N	N	N	N	
Musculoskeletal	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	1	3	
	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	
	MOVEMENTS REDUCED							1	1	
	MUSCLE ATROPHY	2							2	
	MUSCLE PAIN	2						2	4	
	MUSCLE SPASTICITY		1					1	2	
	MUSCLE STIFFNESS	5		1				5	11	
	MUSCLE WASTING							4	4	
	MUSCLE WEAKNESS	84	5	6			3	9	115	

OIA - Cholesterol Lowering Medicines

RGROUP	reaction	Medicine								Total
		ATORVAS-	BEZAFIB-	EZETIMI-	FLUVAST-	GEMFIBR-	PRAVAST-	ROSUVAS-	SIMVAST-	
		TATIN	RATE	BE	ATIN	OZIL	ATIN	TATIN	ATIN	
		N	N	N	N	N	N	N	N	
Musculoskeletal	MUSCULOSKELETAL DISORDER	1								1
	MUSCULOSKELETAL PAIN	2							2	4
	MYALGIA	114	16	28	1	1	1	7	321	489
	MYOPATHY	14	2	1					35	52
	MYOSITIS	10	2						17	29
	MYOSITIS NECROTISING	5								5
	NECK STIFFNESS	1								1
	PAIN IN LIMB								15	15
	PAIN NECK/SHOULDER	3		1					14	18
	POLYARTHRITIS		1							1
	POLYMYOSITIS	1							1	2
	RHABDOMYOLYSIS	14	2		1				53	70
	SKELETAL PAIN	2		1					13	16
	SYNOVITIS	1		1					4	6
	TENDINITIS	3		1					1	5
	TENDON DISORDER								2	2
	*** Total for Group ***	334	37	61	2	1	6	22	798	1261

OIA - Cholesterol Lowering Medicines

RGROUP	reaction	Medicine								Total
		ATORVAS-	BEZAFIB-	EZETIMI-	FLUVAST-	GEMFIBR-	PRAVAST-	ROSUVAS-	SIMVAST-	
		TATIN	RATE	BE	ATIN	OZIL	ATIN	TATIN	ATIN	
		N	N	N	N	N	N	N	N	
Nervous System	ATAXIA	2						22	24	
	BURNING SKIN						1		1	
	CARPAL TUNNEL SYNDROME	1							1	
	CEREBROVASCULAR DISORDER	1							1	
	COGNITIVE FUNCTION ABNORMAL	1						1	2	
	COMA			1					1	
	CONVULSIONS							1	1	
	CONVULSIONS AGGRAVATED	1							1	
	COORDINATION ABNORMAL							2	2	
	DROWSINESS							1	1	
	DYSAESTHESIA	9		2				16	27	
	DYSKINESIA							1	1	
	DYSPRAXIA	1							1	
	ELECTRIC SHOCK SENSATION	1							1	
	ENCEPHALOPATHY							1	1	
	EXTRAPYRAMIDAL DISORDER							1	1	
	FORMICATION	1					1	1	3	

OIA - Cholesterol Lowering Medicines

RGROUP	reaction	Medicine								Total
		ATORVAS-	BEZAFIB-	EZETIMI-	FLUVAST-	GEMFIBR-	PRAVAST-	ROSUVAS-	SIMVAST-	
		TATIN	RATE	BE	ATIN	OZIL	ATIN	TATIN	ATIN	
		N	N	N	N	N	N	N	N	
Nervous System	FUZZY HEAD	1		1						2
	GAIT ABNORMAL	1					1			2
	HEADACHE	29	2	11				2	84	128
	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
	MOBILITY DECREASED	1							4	5
	MONONEURITIS								2	2
	MONOPLÉGIA	1								1
	MUSCLE CONTRACTIONS INVOLUNTARY	1							9	10
	MYOCLONIC JERKS	1								1
	NERVE ROOT LESION								1	1

OIA - Cholesterol Lowering Medicines

RGROUP	reaction	Medicine								Total
		ATORVAS-	BEZAFIB-	EZETIMI-	FLUVAST-	GEMFIBR-	PRAVAST-	ROSUVAS-	SIMVAST-	
		TATIN	RATE	BE	ATIN	OZIL	ATIN	TATIN	ATIN	
		N	N	N	N	N	N	N	N	
Nervous System	NEURITIS SENSORY								1	1
	NEUROMYOPATHY								1	1
	NEUROPATHY								4	4
	NEUROPATHY PERIPHERAL	7		2					13	22
	NUMBNESS LOCALISED	1							5	6
	OCULOGYRIC CRISIS	1							1	2
	PAIN	4							6	10
	PAIN GROIN								1	1
	PAIN IN FACE								1	1
	PARAESTHESIA	4		1			2	1	36	44
	PARAESTHESIA DISTAL	8		1					6	15
	PARAESTHESIA LIPS	1								1
	PARAESTHESIA MOUTH								2	2
	PARAESTHESIA TONGUE								1	1
	PARALYSIS								1	1
	PERIPHERAL NEURITIS								1	1
	POLYNEUROPATHY	1								1

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	RESTLESS LEGS						1		1	2
	SCIATICA			1						1
	SHAKING								2	2
	SPASM GENERALISED								1	1
	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
	*** Total for Group ***	91	5	24			5	4	278	407
Others	reaction									
	ACCIDENT	2						1	4	7
	ALCOHOL INTOLERANCE								1	1
	ALLERGIC REACTION	1							2	3
	ANAPHYLACTIC REACTION	1								1
	ANAPHYLACTOID REACTION	1								1

OIA - Cholesterol Lowering Medicines

RGROUP	reaction	Medicine								Total
		ATORVAS-	BEZAFIB-	EZETIMI-	FLUVAST-	GEMFIBR-	PRAVAST-	ROSUVAS-	SIMVAST-	
		TATIN	RATE	BE	ATIN	OZIL	ATIN	TATIN	ATIN	
		N	N	N	N	N	N	N	N	
Others	BLOOD ALCOHOL EXCESSIVE								1	1
	BONE METASTASES	1								1
	CHILLS	1								1
	DRESS SYNDROME	1								1
	DRUG - ALCOHOL INTERACTION								1	1
	DRUG - FOOD INTERACTION	1							3	4
	DRUG INTERACTION	21	3						71	95
	FACE OEDEMA	2							6	8
	FALL	4							9	13
	FEELING COLD								2	2
	FEELING OF WARMTH								3	3
	FEVER	6		2					5	13
	HEAT INTOLERANCE		1							1
	HEAVINESS IN LIMBS	1								1
	HOT FLUSHES								1	1
	INFLAMMATION			1						1
	INFLUENZA-LIKE SYMPTOMS	2		1				1	6	10

OIA - Cholesterol Lowering Medicines

RGROUP	reaction	Medicine								Total
		ATORVAS-	BEZAFIB-	EZETIMI-	FLUVAST-	GEMFIBR-	PRAVAST-	ROSUVAS-	SIMVAST-	
		TATIN	RATE	BE	ATIN	OZIL	ATIN	TATIN	ATIN	
		N	N	N	N	N	N	N	N	
Others	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
	OEDEMA		2						3	5
	OEDEMA LEGS	2		2					6	10
	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

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	SUDDEN DEATH	2							1	3
	SWEATING INCREASED		1						5	6
	TEMPERATURE CHANGED SENSATION	1	1						2	4
	THERAPEUTIC RESPONSE DECREASED								8	8
	THROAT SWELLING NON-SPECIFIC	1							3	4
	TONGUE OEDEMA	2							6	8
	TONGUE SWELLING NON-SPECIFIC	1							1	2
	UNEXPECTED THERAPEUTIC EFFECT								1	1
	*** Total for Group ***	69	12	7					2	177
Procedure Related	reaction									
	ACCIDENTAL OVERDOSE								1	1
	MEDICATION ERROR	2							19	21
	*** Total for Group ***	2							20	22
Product Related	reaction									
	BRAND SWITCH	60		6			1		148	215
	GENERIC SWITCH	9							10	19
	PACKAGING CHANGE		1							1

OIA - Cholesterol Lowering Medicines

		Medicine								
		ATORVAS-	BEZAFIB-	EZETIMI-	FLUVAST-	GEMFIBR-	PRAVAST-	ROSUVAS-	SIMVAST-	
		TATIN	RATE	BE	ATIN	OZIL	ATIN	TATIN	ATIN	Total
		N	N	N	N	N	N	N	N	N
RGROUP	reaction									
Product Related	PRODUCT FORMULATION CHANGE	13	1						1	15
	PRODUCT PROBLEM			2						2
	PRODUCT STORAGE ERROR	1								1
	*** Total for Group ***	83	2	8		1			159	253
Psychiatric Changes	reaction									
	AGGRESSIVE REACTION	3		2					4	9
	AGITATION								2	2
	AMNESIA	12		3					27	42
	ANGER								3	3
	ANXIETY	1					1		6	8
	ASTHENIA	1		2					12	15
	BEHAVIOUR ABNORMAL								1	1
	COGNITIVE DETERIORATION								2	2
	CONCENTRATION IMPAIRED	3	1				1	2	6	13
	CONFUSION	9		1					15	25
	DEMENTIA	1								1
	DEPERSONALIZATION	2						1	3	6

OIA - Cholesterol Lowering Medicines

RGROUP	reaction	Medicine								Total
		ATORVAS-	BEZAFIB-	EZETIMI-	FLUVAST-	GEMFIBR-	PRAVAST-	ROSUVAS-	SIMVAST-	
		TATIN	RATE	BE	ATIN	OZIL	ATIN	TATIN	ATIN	
		N	N	N	N	N	N	N	N	
Psychiatric Changes	DEPRESSION	13		1			2		31	47
	DISORIENTATION	2	1						4	7
	DREAMING ABNORMAL		1					1	8	10
	EMOTIONAL LABILITY	2					2		4	8
	FATIGUE	23	3	3			2	1	31	63
	HALLUCINATION	2							6	8
	HALLUCINATION AUDITORY								1	1
	HALLUCINATION VISUAL	1		1						2
	INSOMNIA	11		2					16	29
	IRRITABILITY	1		2			1		3	7
	LETHARGY	14	1	7					43	65
	MALaise	9	1	2				2	18	32
	MEMORY DISTURBANCE	1					1			2
	MEMORY IMPAIRMENT	13	1	1			1		17	33
	MEMORY LOSS	12	1						13	26
	MOOD DISORDER	1		1					1	3
	MOOD SWINGS			1					1	2

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	NERVOUSNESS		1						1	2
	PANIC REACTION								1	1
	PARANOID REACTION	1		1						2
	PARONIRIA	2	2	1			2		12	19
	PERSONALITY DISORDER								2	2
	SLEEP DISORDER	1						1	2	4
	SLEEP DISTURBED	2		2					7	11
	SOMNAMBULISM								1	1
	SOMNOLENCE	2		2					8	12
	SUICIDAL TENDENCY								4	4
	SUICIDE								1	1
	SUICIDE ATTEMPT								1	1
	TEARFUL	1								1
	THINKING ABNORMAL								4	4
	TIREDNESS	6		1					22	29
	*** Total for Group ***	152	13	36			13	8	344	566

(Continued)

OIA - Cholesterol Lowering Medicines

RGROUP	reaction	Medicine								Total
		ATORVAS-	BEZAFIB-	EZETIMI-	FLUVAST-	GEMFIBR-	PRAVAST-	ROSUVAS-	SIMVAST-	
		TATIN	RATE	BE	ATIN	OZIL	ATIN	TATIN	ATIN	
		N	N	N	N	N	N	N	N	
Reproductive Disorders	BREAST PAIN								1	1
	BREAST PAIN FEMALE	1							1	2
	BREAST PAIN MALE								4	4
	BREAST TENDERNESS	1								1
	EJACULATION DELAYED		1							1
	ERECTILE DYSFUNCTION								2	2
	GENITAL ULCERATION								1	1
	IMPOTENCE	2	1						7	10
	LIBIDO DECREASED	2							3	5
	LIBIDO INCREASED			1						1
	*** Total for Group ***	6	2	1					19	28
Resistance Mechanism Disorders	ABSCCESS								1	1
	ANTIBODIES DRUG SPECIFIC	9								9
	CANDIDIASIS	1								1
	CELLULITIS	1								1
	SEPSIS								1	1

OIA - Cholesterol Lowering Medicines

RGROUP		Medicine								Total
		ATORVAS-	BEZAFIB-	EZETIMI-	FLUVAST-	GEMFIBR-	PRAVAST-	ROSUVAS-	SIMVAST-	
		TATIN	RATE	BE	ATIN	OZIL	ATIN	TATIN	ATIN	
		N	N	N	N	N	N	N	N	
	*** Total for Group ***									
Resistance Mechanism Disorders		11							2	13
Respiratory	reaction									
	BRONCHITIS								1	1
	BRONCHOSPASM		1						1	2
	BRONCHOSPASM AGGRAVATED	2		1						3
	CORYZA								1	1
	COUGHING	3	1	3			1		14	22
	DYSPNOEA	7	1	1			2		31	42
	HOARSENESS	1								1
	INTERSTITIAL LUNG DISEASE	1						1	1	3
	LOWER RESP TRACT INFECTION	1								1
	NASAL CONGESTION	1	1							2
	NASAL DRYNESS								1	1
	PHARYNGITIS	1							1	2
	PNEUMONIA	1		1					3	5
	PNEUMONIA INTERSTITIAL								1	1
	PNEUMONITIS	1								1

OIA - Cholesterol Lowering Medicines

RGROUP	reaction	Medicine								Total
		ATORVAS-	BEZAFIB-	EZETIMI-	FLUVAST-	GEMFIBR-	PRAVAST-	ROSUVAS-	SIMVAST-	
		TATIN	RATE	BE	ATIN	OZIL	ATIN	TATIN	ATIN	
		N	N	N	N	N	N	N	N	
Respiratory	PULMONARY DISORDERS								1	1
	PULMONARY FIBROSIS	1							1	2
	PULMONARY OEDEMA								1	1
	RESPIRATORY DISORDER								1	1
	RESPIRATORY FAILURE								1	1
	RHINITIS	1							2	3
	SINUSITIS	1							1	2
	SPUTUM INCREASED				1					1
	THROAT IRRITATION	1							1	2
	THROAT TIGHTNESS				1				6	7
	*** Total for Group ***	23	4	8			3	1	70	109
Skin and Appendages	ALOPECIA	6	9	1					34	50
	ALOPECIA AREATA	1							1	2
	ANGIOEDEMA	4	1	1			2		8	16
	BULLOUS ERUPTION	2	2						4	8
	DERMATITIS	2							2	4

OIA - Cholesterol Lowering Medicines

RGROUP	reaction	Medicine								Total
		ATORVAS-	BEZAFIB-	EZETIMI-	FLUVAST-	GEMFIBR-	PRAVAST-	ROSUVAS-	SIMVAST-	
		TATIN	RATE	BE	ATIN	OZIL	ATIN	TATIN	ATIN	
		N	N	N	N	N	N	N	N	
Skin and Appendages	DERMATITIS EXFOLIATIVE								1	1
	DERMATITIS LICHENOID	1								1
	DERMOGRAPHIA	1								1
	ECZEMA	2		1					3	6
	ERYTHEMA	3								3
	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

OIA - Cholesterol Lowering Medicines

RGROUP	reaction	Medicine								Total
		ATORVAS-	BEZAFIB-	EZETIMI-	FLUVAST-	GEMFIBR-	PRAVAST-	ROSUVAS-	SIMVAST-	
		TATIN	RATE	BE	ATIN	OZIL	ATIN	TATIN	ATIN	
		N	N	N	N	N	N	N	N	
Skin and Appendages	NAIL DISORDER								1	1
	PEMPHIGOID REACTION								1	1
	PHOTOSENSITIVITY REACTION	1	4	1					7	13
	PRURITUS	12	1						28	41
	PRURITUS ANI	1								1
	PSORIASIS AGGRAVATED								1	1
	PURPURA		1	1					5	7
	RASH	15	4	3					27	49
	RASH ERYTHEMATOUS	5		3					6	14
	RASH MACULO-PAPULAR	2							2	4
	RASH PETECHIAL								1	1
	RASH PRURITIC	7	3	1					21	32
	RASH PURPURIC								1	1
	RASH PUSTULAR								2	2
	SCAR								1	1
	SKIN DISCOLOURATION	1							1	2
	SKIN DISORDER	1								1

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 DRY	1		1						2
	SKIN EXFOLIATION								1	1
	SKIN IRRITATION	1							1	2
	SKIN NODULE								1	1
	SKIN ODOUR ABNORMAL	1								1
	SKIN ULCERATION								1	1
	TOXIC EPIDERMAL NECROLYSIS	1								1
	URTICARIA	8		1				1	20	30
	VESICULAR RASH			1					1	2
	*** Total for Group ***	92	27	16			3	2	192	332
Special Senses	ANOSMIA	1		1					4	6
	CATARACT								1	1
	CHROMATOPSIA	1								1
	CONJUNCTIVITIS	2							4	6
	DIPLOPIA								4	4
	DRY EYES								1	1

OIA - Cholesterol Lowering Medicines

RGROUP	reaction	Medicine								Total
		ATORVAS-	BEZAFIB-	EZETIMI-	FLUVAST-	GEMFIBR-	PRAVAST-	ROSUVAS-	SIMVAST-	
		TATIN	RATE	BE	ATIN	OZIL	ATIN	TATIN	ATIN	
		N	N	N	N	N	N	N	N	
Special Senses	DYSGEUSIA	2							3	5
	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 LOSS	2		1					1	4
	TASTE METALLIC	1							4	5
	TASTE PERVERSION	2					1		3	6
	TINNITUS	1					1	1	4	7
	TINNITUS AGGRAVATED								1	1
	UVEITIS								1	1
	VISION ABNORMAL		2						8	10
	VISION BLURRED	1		3					9	13

OIA - Cholesterol Lowering Medicines

RGROUP	reaction	Medicine								Total
		ATORVAS-	BEZAFIB-	EZETIMI-	FLUVAST-	GEMFIBR-	PRAVAST-	ROSUVAS-	SIMVAST-	
		TATIN	RATE	BE	ATIN	OZIL	ATIN	TATIN	ATIN	
		N	N	N	N	N	N	N	N	
Special Senses	VISION DECREASED	1								1
	XEROPHTHALMIA								3	3
	*** Total for Group ***	16	2	5			3	1	60	87
Urinary	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
	NOCTURIA	2							2	4
	NOCTURIA AGGRAVATED								1	1
	OLIGURIA								2	2
	POLYURIA	2								2

OIA - Cholesterol Lowering Medicines

RGROUP	reaction	Medicine								Total
		ATORVAS-	BEZAFIB-	EZETIMI-	FLUVAST-	GEMFIBR-	PRAVAST-	ROSUVAS-	SIMVAST-	
		TATIN	RATE	BE	ATIN	OZIL	ATIN	TATIN	ATIN	
		N	N	N	N	N	N	N	N	
Urinary	PROSTATIC DISORDER		1							1
	RENAL FAILURE ACUTE	1	2					29		32
	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	4								4
	RENAL PAIN							3		3
	RENAL TUBULAR NECROSIS	1								1
	RETROPERITONEAL FIBROSIS	1								1
	URINE ABNORMAL							3		3
	URINE DISCOLOURATION	4						1		5
	URINE FLOW DECREASED	1								1
	URINE ODOUR FOUL	1		1				1		3
	*** Total for Group ***	21	15	2			3		67	108
Total Reactions		1226	186	265	3	5	43	55	2937	4720