



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**
29 July 2013

Period Covered: This search covers all spontaneous reports received by the Centre for Adverse Reactions Monitoring [CARM] from 01 January 2001 to 30 June 2013

Request Details: “...the number of adverse reactions to all brands of statins including fatalities in the period 2001 – 2013 or present date.”

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

Summary: Statin medicines in New Zealand:
 atorvastatin
 fluvastatin
 pravastatin
 rosuvastatin
 simvastatin

This document details 1539 reports describing 3454 reaction terms - one report may have more than one reaction described.

21 cases resulted in an outcome of death however in 3 cases death was not related to the Statin medicine and 2 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 June 2013 the following reports were received:

| | |
|--------------|------|
| Atorvastatin | 324 |
| Fluvastatin | 3 |
| Pravastatin | 5 |
| Rosuvastatin | 13 |
| Simvastatin | 1194 |

Reports:

The breakdown per year was:

| Year | Atorvastatin | Fluvastatin | Pravastatin | Rosuvastatin | Simvastatin | Total |
|--------------|--------------|-------------|-------------|--------------|-------------|-------------|
| 2001 | 25 | 3 | | | 13 | 41 |
| 2002 | 23 | | | | 56 | 79 |
| 2003 | 9 | | | | 73 | 82 |
| 2004 | 14 | | | | 143 | 157 |
| 2005 | 9 | | | | 166 | 175 |
| 2006 | 7 | | | | 205 | 212 |
| 2007 | 18 | | | | 103 | 121 |
| 2008 | 15 | | | | 85 | 100 |
| 2009 | 20 | | | 2 | 190 | 212 |
| 2010 | 22 | | | | 59 | 81 |
| 2011 | 46 | | | 4 | 33 | 83 |
| 2012 | 87 | | 2 | 5 | 51 | 145 |
| 2013 | 29 | | 3 | 2 | 17 | 51 |
| Total | 324 | 3 | 5 | 13 | 1194 | 1539 |

Fatalities:

Analysis of 21 cases resulting in death

| Outcome | Atorvastatin | Simvastatin | Total |
|-----------------------------------|--------------|-------------|-------|
| Died due to the adverse reaction | | 7 | 7 |
| Died medicine may be contributory | 2 | 7 | 9 |
| Died – cause unclassifiable | | 2 | 2 |
| 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 attached listing:

Statins

| | | Medicine | | | | | Total |
|-------------------------|--------------------------------|---------------|--------------|--------------|---------------|--------------|-------|
| | | ATORVAS-TATIN | FLUVAST-ATIN | PRAVAST-ATIN | ROSUVAS-TATIN | SIMVAST-ATIN | |
| | | N | N | N | N | N | |
| RGROUP | reaction | | | | | | |
| Alimentary | ABDOMEN ENLARGED | 1 | | | | 1 | 2 |
| | ABDOMINAL DISTENSION | | | | | 3 | 3 |
| | ABDOMINAL PAIN | 13 | | | 1 | 50 | 64 |
| | AGEUSIA | | | | | 2 | 2 |
| | ANOREXIA | 1 | | | | 4 | 5 |
| | APPETITE DECREASED | | | | | 1 | 1 |
| | APPETITE INCREASED | | | | | 1 | 1 |
| | BLOATING | 1 | | | | 5 | 6 |
| | BOWEL MOTILITY DISORDER | | | | | 1 | 1 |
| | BURNING SENSATION | 1 | | | | | 1 |
| | CHANGE IN BOWEL HABITS | | | | | 2 | 2 |
| | CHEILITIS | | | | | 1 | 1 |
| | CHOLELITHIASIS | 2 | | | | 1 | 3 |
| | COLIC ABDOMINAL | | | | | 1 | 1 |
| | COLITIS | | | | | 1 | 1 |
| | CONSTIPATION | 4 | | | | 22 | 26 |
| | CRAMP ABDOMINAL | | | | | 1 | 1 |
| | DIARRHOEA | 6 | | | 1 | 40 | 47 |
| | DYSPEPSIA | | | 1 | | 22 | 23 |
| | DYSPHAGIA | 2 | | | | 3 | 5 |
| | ERUCTATION | | | | | 4 | 4 |
| | FAECAL INCONTINENCE | | | | | 3 | 3 |
| | FLATULENCE | 2 | | | | 16 | 18 |
| | GASTRIC ULCER | | | | | 2 | 2 |
| | GASTRIC ULCER HAEMORRHAGIC | | | | | 1 | 1 |
| | GASTRO-INTESTINAL DISORDER NOS | 3 | | | | | 3 |
| | GASTROENTERITIS | | | | | 1 | 1 |
| GASTROESOPHAGEAL REFLUX | 1 | | | | 4 | 5 | |
| GINGIVITIS | 1 | | | | | 1 | |
| GLOSSITIS | 2 | | | | | 2 | |
| HAEMORRHAGE RECTUM | | | | | 1 | 1 | |

(Continued)

Statins

| | | Medicine | | | | | Total |
|-------------------------|-----------------------------|---------------|--------------|--------------|---------------|--------------|-------|
| | | ATORVAS-TATIN | FLUVAST-ATIN | PRAVAST-ATIN | ROSUVAS-TATIN | SIMVAST-ATIN | |
| | | N | N | N | N | N | |
| RGROUP | reaction | | | | | | |
| Alimentary | HAEMORRHOIDS | | | | | 1 | 1 |
| | IRRITABLE BOWEL SYNDROME | | | | | 1 | 1 |
| | LIP DISORDER | 1 | | | | | 1 |
| | MELAENA | 1 | | | | | 1 |
| | MOUTH DRY | 3 | | | | 7 | 10 |
| | NAUSEA | 16 | | 1 | 1 | 59 | 77 |
| | PANCREAS NEOPLASM MALIGNANT | 1 | | | | | 1 |
| | PROCTALGIA | | | | | 2 | 2 |
| | RECTAL BLEEDING | | | | | 2 | 2 |
| | RECTAL DISORDER | 1 | | | | | 1 |
| | STOMATITIS | | | | | 3 | 3 |
| | STOMATITIS ULCERATIVE | | | | | 2 | 2 |
| | THROAT DRY | | | | | 2 | 2 |
| | TONGUE DISCOLOURATION | | | | | 1 | 1 |
| | TONGUE GEOGRAPHIC | | | | | 1 | 1 |
| | TONGUE PAIN | | | | | 3 | 3 |
| | TONGUE ULCERATION | | | | | 1 | 1 |
| | TOOTH ABSCESS | | | | | 1 | 1 |
| | TOOTH ACHE | | | | | 2 | 2 |
| | TOOTH DISCOLOURATION | | | | | 1 | 1 |
| VOMITING | 2 | | | 1 | 23 | 26 | |
| *** Total for Group *** | 65 | | 2 | 4 | 306 | 377 | |
| Application Site | reaction | | | | | | |
| | LIPODYSTROPHY | | | | | 1 | 1 |
| | *** Total for Group *** | | | | | 1 | 1 |
| Cardiovascular | reaction | | | | | | |
| | ANGINA PECTORIS | | | | | 1 | 1 |
| | ANGINA PECTORIS AGGRAVATED | 2 | | | | | 2 |
| | ARRHYTHMIA | | | | | 2 | 2 |
| | ATRIAL FIBRILLATION | | | | | 1 | 1 |
| | BRADYCARDIA | 1 | | | | 1 | 2 |

(Continued)

Statins

| | | Medicine | | | | | Total |
|----------------|------------------------------|---------------|--------------|--------------|---------------|--------------|-------|
| | | ATORVAS-TATIN | FLUVAST-ATIN | PRAVAST-ATIN | ROSUVAS-TATIN | SIMVAST-ATIN | |
| | | N | N | N | N | N | |
| RGROUP | reaction | | | | | | |
| Cardiovascular | CARDIAC ARREST | 2 | | | | 1 | 3 |
| | CARDIAC FAILURE | | | | | 3 | 3 |
| | CARDIOMYOPATHY | | | | | 1 | 1 |
| | CARDIOVASCULAR DISORDERS | | | | | 1 | 1 |
| | CHEST DISCOMFORT | 2 | | | | | 2 |
| | CHEST PAIN | 6 | | | 1 | 19 | 26 |
| | CHEST TIGHTNESS | 1 | | | | 2 | 3 |
| | COLLAPSE CIRCULATORY | 1 | | | | | 1 |
| | CONGESTIVE HEART FAILURE | | | | | 1 | 1 |
| | DIZZINESS | 7 | | 2 | 2 | 42 | 53 |
| | ECG ABNORMAL | 1 | | | | | 1 |
| | FAINTNESS | 1 | | | | | 1 |
| | FLUSHING | 1 | | | | 5 | 6 |
| | HEART DISORDER | 1 | | | | | 1 |
| | HYPERTENSION | 1 | | | | 4 | 5 |
| | HYPERTENSION AGGRAVATED | | | | | 2 | 2 |
| | HYPOTENSION | 1 | | | | 3 | 4 |
| | HYPOTENSION POSTURAL | 1 | | | | | 1 |
| | MYOCARDIAL INFARCTION | 1 | | | | | 1 |
| | MYOCARDITIS | | | | | 1 | 1 |
| | PALPITATION | 3 | | | | 11 | 14 |
| | PERIPHERAL COLDNESS | 1 | | | | | 1 |
| | PERIPHERAL ISCHAEMIA | 1 | | | | | 1 |
| | SYNCOPE | 1 | | | | 6 | 7 |
| | TACHYCARDIA | 1 | | | | 1 | 2 |
| | TACHYCARDIA VENTRICULAR | 1 | | | | | 1 |
| | THROMBOPHLEBITIS SUPERFICIAL | | | | | 1 | 1 |
| | THROMBOSIS ARTERIAL | | | | | 1 | 1 |
| | VASCULITIS | | | | | 2 | 2 |
| | VASOCONSTRICTION | 1 | | | | | 1 |
| VASODILATION | | | | | 1 | 1 | |

(Continued)

Statins

| | | Medicine | | | | | Total |
|---------------------|----------------------------------|---------------|--------------|--------------|---------------|--------------|-------|
| | | ATORVAS-TATIN | FLUVAST-ATIN | PRAVAST-ATIN | ROSUVAS-TATIN | SIMVAST-ATIN | |
| | | N | N | N | N | N | |
| RGROUP | reaction | | | | | | |
| Cardiovascular | VEIN DISTENDED | | | | | 1 | 1 |
| | *** Total for Group *** | 39 | | 2 | 3 | 114 | 158 |
| Collagen Disorders | reaction | | | | | | |
| | ANTINUCLEAR FACTOR TEST POSITIVE | 2 | | | | 1 | 3 |
| | *** Total for Group *** | 2 | | | | 1 | 3 |
| Endocrine/Metabolic | reaction | | | | | | |
| | AMYLASE INCREASED | | | | | 3 | 3 |
| | BREAST ENLARGEMENT | | | | | 1 | 1 |
| | BREAST ENLARGEMENT MALE | | | | | 2 | 2 |
| | CREATINE PHOSPHOKINASE INCREASED | 21 | | | 1 | 88 | 110 |
| | CREATININE BLOOD INCREASED | | | | | 2 | 2 |
| | DEHYDRATION | | | | | 1 | 1 |
| | DIABETES MELLITUS | 1 | | | | 1 | 2 |
| | DIABETES MELLITUS AGGRAVATED | 3 | | | | | 3 |
| | DIABETIC KETOACIDOSIS | | | | | 1 | 1 |
| | ELECTROLYTE ABNORMALITY | 1 | | | | | 1 |
| | ERECTILE DYSFUNCTION | | | | | 2 | 2 |
| | FAT ATROPHY | | | | | 2 | 2 |
| | GOUT | | | | | 2 | 2 |
| | GOUT AGGRAVATED | | | | | 2 | 2 |
| | GYNAECOMASTIA | 3 | | | | 5 | 8 |
| | HDL DECREASED | | | | | 1 | 1 |
| | HYPERCHOLESTEROLAEMIA | | | | | 1 | 1 |
| | HYPERGLYCAEMIA | 1 | | | | 4 | 5 |
| | HYPERKALAEMIA | | | | | 2 | 2 |
| | HYPOGLYCAEMIA | 1 | | | 1 | 2 | 4 |
| | IMPOTENCE | 2 | | | | 7 | 9 |
| | LDH INCREASED | | | | | 1 | 1 |
| MYOGLOBINURIA | | | | | 1 | 1 | |
| PANCREATITIS | 2 | | | | 10 | 12 | |
| PEYRONIES DISEASE | | | | | 1 | 1 | |

(Continued)

Statins

| | | Medicine | | | | | Total |
|---------------------|-----------------------------|---------------|--------------|--------------|---------------|--------------|-------|
| | | ATORVAS-TATIN | FLUVAST-ATIN | PRAVAST-ATIN | ROSUVAS-TATIN | SIMVAST-ATIN | |
| | | N | N | N | N | N | |
| RGROUP | reaction | | | | | | |
| Endocrine/Metabolic | PLASMA OSMOLALITY INCREASED | | | | | 1 | 1 |
| | POLYDIPSIA | | | | | 1 | 1 |
| | SERUM FERRITIN INCREASED | 1 | | | | | 1 |
| | TESTOSTERONE DECREASED | | | | | 1 | 1 |
| | THIRST | | | | | 2 | 2 |
| | THYROID DISORDER | | | | | 2 | 2 |
| | TROPONIN T INCREASED | | | | | 2 | 2 |
| | WEIGHT DECREASE | 4 | | | | 7 | 11 |
| | WEIGHT INCREASE | 2 | | | | 5 | 7 |
| | *** Total for Group *** | 42 | | | 2 | 163 | 207 |
| Foetal Disorders | reaction | | | | | | |
| | FOETAL DISORDERS | 1 | | | | | 1 |
| | *** Total for Group *** | 1 | | | | | 1 |
| Haematological | reaction | | | | | | |
| | ANAEMIA | 3 | | | | 3 | 6 |
| | ANAEMIA APLASTIC | | | | | 1 | 1 |
| | ANAEMIA HAEMOLYTIC | | | | | 1 | 1 |
| | C-REACTIVE PROTEIN POSITIVE | | | | | 5 | 5 |
| | EOSINOPHILIA | 1 | | | | 1 | 2 |
| | EPISTAXIS | | | | | 7 | 7 |
| | ESR INCREASED | 1 | | | | 1 | 2 |
| | HAEMORRHAGE NOS | 1 | | | | | 1 |
| | INR DECREASED | 1 | | | | | 1 |
| | INR INCREASED | 1 | | | | 1 | 2 |
| | LEUKOCYTOSIS | | | | | 2 | 2 |
| | THROMBOCYTOPENIA | 1 | 1 | | 1 | | 3 |
| | THROMBOCYTOSIS | | | | | 1 | 1 |
| | *** Total for Group *** | 9 | 1 | | 1 | 23 | 34 |
| Liver | reaction | | | | | | |
| | BILIRUBINAEMIA | 1 | | | | 1 | 2 |
| | BILIRUBINURIA | 1 | | | | | 1 |

(Continued)

Statins

| | | Medicine | | | | | Total |
|-------------------------|----------------------------|---------------|--------------|--------------|---------------|--------------|-------|
| | | ATORVAS-TATIN | FLUVAST-ATIN | PRAVAST-ATIN | ROSUVAS-TATIN | SIMVAST-ATIN | |
| | | N | N | N | N | N | |
| RGROUP | reaction | | | | | | |
| Liver | HEPATIC CIRRHOSIS | | | | | 1 | 1 |
| | HEPATIC CYST | | | | | 1 | 1 |
| | HEPATIC ENZYMES INCREASED | 22 | | | | 39 | 61 |
| | HEPATIC FAILURE | | | | | 3 | 3 |
| | HEPATIC FUNCTION ABNORMAL | 8 | | | | 14 | 22 |
| | HEPATIC NEOPLASM MALIGNANT | 1 | | | | | 1 |
| | HEPATITIS | 2 | | | | 3 | 5 |
| | HEPATITIS CHOLESTATIC | 3 | | | | 4 | 7 |
| | HEPATITIS VIRAL | 1 | | | | | 1 |
| | HEPATOCELLULAR DAMAGE | 2 | | | | 8 | 10 |
| | HEPATOMEGALY | | | | | 2 | 2 |
| | HYPERBILIRUBINAEMIA | | | | | 1 | 1 |
| | JAUNDICE | 2 | | | | 9 | 11 |
| | LIVER FATTY | 1 | | | | 1 | 2 |
| | SGOT INCREASED | | | | | 1 | 1 |
| *** Total for Group *** | | 44 | | | | 88 | 132 |
| Musculoskeletal | reaction | | | | | | |
| | ARTHRALGIA | 17 | | | 1 | 80 | 98 |
| | ARTHRITIS | | | | 1 | 7 | 8 |
| | ARTHRITIS RHEUMATOID | | | | | 1 | 1 |
| | ARTHROPATHY | 1 | | | | 1 | 2 |
| | BACK PAIN | 5 | | | | 31 | 36 |
| | BONE DISORDER | | | | | 1 | 1 |
| | BURSITIS | 2 | | | | | 2 |
| | CALF PAIN | 1 | | | | | 1 |
| | CRAMPS | 7 | | | | 31 | 38 |
| | CRAMPS LEGS | 1 | | | | 11 | 12 |
| | FASCITIS PLANTAR | | | | | 1 | 1 |
| | JAW PAIN | | | | | 3 | 3 |
| | JOINT EFFUSION | | | | | 1 | 1 |
| | JOINT PAIN | | | | | 1 | 1 |

(Continued)

Statins

| | | Medicine | | | | | Total |
|-----------------|---------------------------------|---------------|--------------|--------------|---------------|--------------|-------|
| | | ATORVAS-TATIN | FLUVAST-ATIN | PRAVAST-ATIN | ROSUVAS-TATIN | SIMVAST-ATIN | |
| | | N | N | N | N | N | |
| RGROUP | reaction | | | | | | |
| Musculoskeletal | JOINT STIFFNESS | 2 | | | | 3 | 5 |
| | JOINT SWELLING NON-INFLAMMATORY | 1 | | | | 2 | 3 |
| | LEG PAIN | 2 | | | | 14 | 16 |
| | LUMBAR DISC LESION | | | | | 1 | 1 |
| | MUSCLE ATROPHY | 2 | | | | | 2 |
| | MUSCLE PAIN | | | | | 1 | 1 |
| | MUSCLE SPASTICITY | | | | | 1 | 1 |
| | MUSCLE STIFFNESS | 1 | | | | 5 | 6 |
| | MUSCLE WASTING | | | | | 3 | 3 |
| | MUSCLE WEAKNESS | 29 | | 1 | | 78 | 108 |
| | MUSCULOSKELETAL DISORDER | 1 | | | | | 1 |
| | MUSCULOSKELETAL PAIN | | | | | 2 | 2 |
| | MYALGIA | 68 | 1 | 1 | 2 | 299 | 371 |
| | MYOPATHY | 3 | | | | 27 | 30 |
| | MYOSITIS | 5 | | | | 15 | 20 |
| | PAIN IN LIMB | | | | | 15 | 15 |
| | PAIN NECK/SHOULDER | 2 | | | | 14 | 16 |
| | POLYMYOSITIS | | | | | 1 | 1 |
| | RHABDOMYOLYSIS | 4 | 1 | | | 46 | 51 |
| | SKELETAL PAIN | 2 | | | | 13 | 15 |
| | SYNOVITIS | 1 | | | | 4 | 5 |
| TENDINITIS | 2 | | | | 1 | 3 | |
| TENDON DISORDER | | | | | 1 | 1 | |
| | *** Total for Group *** | 159 | 2 | 2 | 4 | 715 | 882 |
| Nervous System | reaction | | | | | | |
| | ATAXIA | | | | | 14 | 14 |
| | BURNING SKIN | | | 1 | | | 1 |
| | CEREBROVASCULAR DISORDER | 1 | | | | | 1 |
| | COGNITIVE FUNCTION ABNORMAL | 1 | | | | 1 | 2 |
| | CONVULSIONS AGGRAVATED | 1 | | | | | 1 |
| | DROWSINESS | | | | | 1 | 1 |

(Continued)

Statins

| | | Medicine | | | | | Total |
|---------------------|---------------------------------|---------------|--------------|--------------|---------------|--------------|-------|
| | | ATORVAS-TATIN | FLUVAST-ATIN | PRAVAST-ATIN | ROSUVAS-TATIN | SIMVAST-ATIN | |
| | | N | N | N | N | N | |
| RGROUP | reaction | | | | | | |
| Nervous System | DYSAESTHESIA | 7 | | | | 16 | 23 |
| | DYSKINESIA | | | | | 1 | 1 |
| | ELECTRIC SHOCK SENSATION | 1 | | | | | 1 |
| | EXTRAPYRAMIDAL DISORDER | | | | | 1 | 1 |
| | FORMICATION | 1 | | | 1 | 1 | 3 |
| | HEADACHE | 20 | | | 2 | 81 | 103 |
| | HEADACHE VASOMOTOR | | | | | 1 | 1 |
| | HYPERAESTHESIA | | | | | 1 | 1 |
| | HYPERKINESIA | | | | | 5 | 5 |
| | HYPERTONIA | 1 | | | | 7 | 8 |
| | HYPOAESTHESIA | 2 | | | | 12 | 14 |
| | HYPOTONIA | | | | | 1 | 1 |
| | LIMB WEAKNESS | | | | | 1 | 1 |
| | MIGRAINE | | | | | 3 | 3 |
| | MOBILITY DECREASED | | | | | 1 | 1 |
| | MONONEURITIS | | | | | 2 | 2 |
| | MONOPLÉGIA | 1 | | | | | 1 |
| | MUSCLE CONTRACTIONS INVOLUNTARY | 1 | | | | 9 | 10 |
| | NERVE ROOT LESION | | | | | 1 | 1 |
| | NEUROMYOPATHY | | | | | 1 | 1 |
| | NEUROPATHY | | | | | 4 | 4 |
| | NEUROPATHY PERIPHERAL | 7 | | | | 12 | 19 |
| | NUMBNESS LOCALISED | 1 | | | | 5 | 6 |
| | OCULOGYRIC CRISIS | | | | | 1 | 1 |
| | PAIN | 1 | | | | 6 | 7 |
| | PAIN GROIN | | | | | 1 | 1 |
| PAIN IN FACE | | | | | 1 | 1 | |
| PARAESTHESIA | 4 | | 1 | 1 | 36 | 42 | |
| PARAESTHESIA DISTAL | 6 | | | | 4 | 10 | |
| PARAESTHESIA MOUTH | | | | | 2 | 2 | |
| PARAESTHESIA TONGUE | | | | | 1 | 1 | |

(Continued)

Statins

| | | Medicine | | | | | Total |
|----------------------------|----------------------------|---------------|--------------|--------------|---------------|--------------|-------|
| | | ATORVAS-TATIN | FLUVAST-ATIN | PRAVAST-ATIN | ROSUVAS-TATIN | SIMVAST-ATIN | |
| | | N | N | N | N | N | |
| RGROUP | reaction | | | | | | |
| Nervous System | PERIPHERAL NEURITIS | | | | | 1 | 1 |
| | POLYNEUROPATHY | 1 | | | | | 1 |
| | RESTLESS LEGS | | | | | 1 | 1 |
| | SHAKING | | | | | 2 | 2 |
| | SOMNAMBULISM | | | | | 1 | 1 |
| | SPASM GENERALISED | | | | | 1 | 1 |
| | SPEECH DISORDER | | | | | 1 | 1 |
| | TRANSIENT ISCHAEMIC ATTACK | | | | | 1 | 1 |
| | TREMOR | 3 | | | | 4 | 7 |
| | URINARY INCONTINENCE | | | | | 1 | 1 |
| | VERTIGO | 2 | | | | 4 | 6 |
| | *** Total for Group *** | 62 | | 2 | 4 | 251 | 319 |
| | Others | reaction | | | | | |
| ALCOHOL INTOLERANCE | | | | | | 1 | 1 |
| ALLERGIC REACTION | | 1 | | | | 1 | 2 |
| ANAPHYLACTOID REACTION | | 1 | | | | | 1 |
| ANGIOEDEMA | | 2 | | 1 | | 8 | 11 |
| BLOOD ALCOHOL EXCESSIVE | | | | | | 1 | 1 |
| CHILLS | | 1 | | | | | 1 |
| DRUG - ALCOHOL INTERACTION | | | | | | 1 | 1 |
| DRUG - FOOD INTERACTION | | 1 | | | | 1 | 2 |
| DRUG INTERACTION | | 11 | | | | 59 | 70 |
| FACE OEDEMA | | 1 | | | | 5 | 6 |
| FALL | | 3 | | | | 9 | 12 |
| FEELING COLD | | | | | | 1 | 1 |
| FEELING OF WARMTH | | | | | | 3 | 3 |
| FEVER | | 5 | | | | 5 | 10 |
| HOT FLUSHES | | | | | | 1 | 1 |
| INFLUENZA-LIKE SYMPTOMS | | 2 | | | 1 | 6 | 9 |
| LIPS SWELLING NON-SPECIFIC | | | | | | 2 | 2 |
| NIGHT SWEATS | | | | | 1 | 1 | |

(Continued)

Statins

| | | Medicine | | | | | Total |
|-------------------|-----------------------------------|---------------|--------------|--------------|---------------|--------------|-------|
| | | ATORVAS-TATIN | FLUVAST-ATIN | PRAVAST-ATIN | ROSUVAS-TATIN | SIMVAST-ATIN | |
| | | N | N | N | N | N | |
| RGROUP | reaction | | | | | | |
| Others | OEDEMA | | | | | 3 | 3 |
| | OEDEMA LEGS | 1 | | | | 6 | 7 |
| | OEDEMA MOUTH | 1 | | | | 3 | 4 |
| | OEDEMA PERIORBITAL | 2 | | | | 3 | 5 |
| | OEDEMA PERIPHERAL | 2 | | | | 9 | 11 |
| | PALLOR | | | | | 1 | 1 |
| | POLYMYALGIA RHEUMATICA | 1 | | | | 1 | 2 |
| | POLYMYALGIA RHEUMATICA AGGRAVATED | 1 | | | | | 1 |
| | PRIAPISM | 1 | | | | 1 | 2 |
| | RIGORS | | | | | 1 | 1 |
| | SNORING | | | | | 1 | 1 |
| | SUDDEN DEATH | | | | | 1 | 1 |
| | SWEATING INCREASED | 1 | | | | 5 | 6 |
| | TEMPERATURE CHANGED SENSATION | 1 | | | | 2 | 3 |
| | THERAPEUTIC RESPONSE DECREASED | | | | | 8 | 8 |
| | THROAT SWELLING NON-SPECIFIC | 1 | | | | 3 | 4 |
| | TONGUE OEDEMA | 2 | | | | 6 | 8 |
| | TONGUE SWELLING NON-SPECIFIC | | | | | 1 | 1 |
| | UNEXPECTED THERAPEUTIC EFFECT | | | | | 1 | 1 |
| | *** Total for Group *** | 42 | | 1 | 1 | 161 | 205 |
| Procedure Related | reaction | | | | | | |
| | ACCIDENTAL OVERDOSE | | | | | 1 | 1 |
| | MEDICATION ERROR | | | | | 13 | 13 |
| | *** Total for Group *** | | | | | 14 | 14 |
| Product Related | reaction | | | | | | |
| | BRAND SWITCH | 27 | | | | 144 | 171 |
| | GENERIC SWITCH | 8 | | | | 10 | 18 |
| | PRODUCT FORMULATION CHANGE | 13 | | | | 1 | 14 |
| | PRODUCT STORAGE ERROR | 1 | | | | | 1 |
| | *** Total for Group *** | 49 | | | | 155 | 204 |

(Continued)

Statins

| | | Medicine | | | | | Total |
|---------------------|-------------------------|---------------|--------------|--------------|---------------|--------------|-------|
| | | ATORVAS-TATIN | FLUVAST-ATIN | PRAVAST-ATIN | ROSUVAS-TATIN | SIMVAST-ATIN | |
| | | N | N | N | N | N | |
| RGROUP | reaction | | | | | | |
| Psychiatric Changes | AGGRESSIVE REACTION | 3 | | | | 4 | 7 |
| | AGITATION | | | | | 2 | 2 |
| | AMNESIA | 12 | | | | 27 | 39 |
| | ANGER | | | | | 2 | 2 |
| | ANXIETY | 1 | | | | 6 | 7 |
| | ASTHENIA | 1 | | | | 11 | 12 |
| | BEHAVIOUR ABNORMAL | | | | | 1 | 1 |
| | COGNITIVE DETERIORATION | | | | | 2 | 2 |
| | CONCENTRATION IMPAIRED | 2 | | | 2 | 6 | 10 |
| | CONFUSION | 7 | | | | 15 | 22 |
| | DEMENTIA | 1 | | | | | 1 |
| | DEPERSONALIZATION | 2 | | | 1 | 3 | 6 |
| | DEPRESSION | 8 | | | | 30 | 38 |
| | DISORIENTATION | 2 | | | | 3 | 5 |
| | DREAMING ABNORMAL | | | | 1 | 8 | 9 |
| | EMOTIONAL LABILITY | 1 | | | | 4 | 5 |
| | FATIGUE | 9 | | | 1 | 31 | 41 |
| | HALLUCINATION | 2 | | | | 6 | 8 |
| | HALLUCINATION AUDITORY | | | | | 1 | 1 |
| | HALLUCINATION VISUAL | 1 | | | | | 1 |
| | INSOMNIA | 10 | | | | 16 | 26 |
| | IRRITABILITY | 1 | | | | 3 | 4 |
| | LETHARGY | 8 | | | | 42 | 50 |
| | MALAISE | 7 | | | 2 | 17 | 26 |
| | MEMORY DISTURBANCE | | | 1 | | | 1 |
| | MEMORY IMPAIRMENT | 7 | | | | 15 | 22 |
| MEMORY LOSS | 9 | | | | 10 | 19 | |
| MOOD DISORDER | 1 | | | | 1 | 2 | |
| NERVOUSNESS | | | | | 1 | 1 | |
| PANIC REACTION | | | | | 1 | 1 | |
| PARANOID REACTION | 1 | | | | | 1 | |

(Continued)

Statins

| | | Medicine | | | | | Total |
|--------------------------------|---------------------------|---------------|--------------|--------------|---------------|--------------|-------|
| | | ATORVAS-TATIN | FLUVAST-ATIN | PRAVAST-ATIN | ROSUVAS-TATIN | SIMVAST-ATIN | |
| | | N | N | N | N | N | |
| RGROUP | reaction | | | | | | |
| Psychiatric Changes | PARONIRIA | | | | | 12 | 12 |
| | PERSONALITY DISORDER | | | | | 2 | 2 |
| | SLEEP DISORDER | | | | 1 | 2 | 3 |
| | SLEEP DISTURBED | | | | | 7 | 7 |
| | SOMNOLENCE | 1 | | | | 8 | 9 |
| | SUICIDAL TENDENCY | | | | | 4 | 4 |
| | SUICIDE | | | | | 1 | 1 |
| | SUICIDE ATTEMPT | | | | | 1 | 1 |
| | THINKING ABNORMAL | | | | | 3 | 3 |
| | TIREDNESS | 1 | | | | 22 | 23 |
| | *** Total for Group *** | 98 | | 1 | 8 | 330 | 437 |
| Reproductive Disorders | reaction | | | | | | |
| | BREAST PAIN | | | | | 1 | 1 |
| | BREAST PAIN FEMALE | 1 | | | | 1 | 2 |
| | BREAST PAIN MALE | | | | | 4 | 4 |
| | BREAST TENDERNESS | 1 | | | | | 1 |
| | GENITAL ULCERATION | | | | | 1 | 1 |
| | LIBIDO DECREASED | 2 | | | | 3 | 5 |
| | *** Total for Group *** | 4 | | | | 10 | 14 |
| Resistance Mechanism Disorders | reaction | | | | | | |
| | SEPSIS | | | | | 1 | 1 |
| | *** Total for Group *** | | | | | 1 | 1 |
| Respiratory | reaction | | | | | | |
| | BRONCHITIS | | | | | 1 | 1 |
| | BRONCHOSPASM | | | | | 1 | 1 |
| | BRONCHOSPASM AGGRAVATED | 2 | | | | | 2 |
| | CORYZA | | | | | 1 | 1 |
| | COUGHING | 2 | | | | 13 | 15 |
| | DYSPNOEA | 5 | | | | 29 | 34 |
| | HOARSENESS | 1 | | | | | 1 |
| | INTERSTITIAL LUNG DISEASE | | | | | 1 | 1 |

(Continued)

Statins

| | | Medicine | | | | | Total |
|---------------------|------------------------------|---------------|--------------|--------------|---------------|--------------|-------|
| | | ATORVAS-TATIN | FLUVAST-ATIN | PRAVAST-ATIN | ROSUVAS-TATIN | SIMVAST-ATIN | |
| | | N | N | N | N | N | |
| RGROUP | reaction | | | | | | |
| Respiratory | NASAL CONGESTION | 1 | | | | | 1 |
| | NASAL DRYNESS | | | | | 1 | 1 |
| | PHARYNGITIS | 1 | | | | 1 | 2 |
| | PNEUMONIA | | | | | 3 | 3 |
| | PNEUMONIA INTERSTITIAL | | | | | 1 | 1 |
| | PULMONARY DISORDERS | | | | | 1 | 1 |
| | PULMONARY OEDEMA | | | | | 1 | 1 |
| | RESPIRATORY DISORDER | | | | | 1 | 1 |
| | RESPIRATORY FAILURE | | | | | 1 | 1 |
| | RHINITIS | 1 | | | | 2 | 3 |
| | SINUSITIS | 1 | | | | 1 | 2 |
| | THROAT IRRITATION | 1 | | | | 1 | 2 |
| | THROAT TIGHTNESS | | | | | 6 | 6 |
| | *** Total for Group *** | | 15 | | | | 66 |
| Skin and Appendages | reaction | | | | | | |
| | ALOPECIA | 5 | | | | 34 | 39 |
| | ALOPECIA AREATA | | | | | 1 | 1 |
| | BULLOUS ERUPTION | 1 | | | | 4 | 5 |
| | DERMATITIS | 2 | | | | 2 | 4 |
| | DERMATITIS EXFOLIATIVE | | | | | 1 | 1 |
| | DERMATITIS LICHENOID | 1 | | | | | 1 |
| | ECZEMA | 2 | | | | 3 | 5 |
| | ERYTHEMA | 3 | | | | | 3 |
| | ERYTHEMA MULTIFORME | 1 | | | | 2 | 3 |
| | HAIR DISORDER NOS | | | | | 1 | 1 |
| | HAIR LOSS | 3 | | | | 4 | 7 |
| | HAIR TEXTURE ABNORMAL | 1 | | | | 1 | 2 |
| | HAIR THINNING | | | | 1 | | 1 |
| | LE SYNDROME | 1 | | | | 1 | 2 |
| | LUPUS ERYTHEMATOSUS SYSTEMIC | 1 | | | | | 1 |
| MACULAR RASH | 1 | | | | | 1 | |

(Continued)

Statins

| | | Medicine | | | | | Total |
|-------------------------|----------------------------|---------------|--------------|--------------|---------------|--------------|-------|
| | | ATORVAS-TATIN | FLUVAST-ATIN | PRAVAST-ATIN | ROSUVAS-TATIN | SIMVAST-ATIN | |
| | | N | N | N | N | N | |
| RGROUP | reaction | | | | | | |
| Skin and Appendages | NAIL DISORDER | | | | | 1 | 1 |
| | PEMPHIGOID REACTION | | | | | 1 | 1 |
| | PHOTOSENSITIVITY REACTION | 1 | | | | 5 | 6 |
| | PRURITUS | 7 | | | | 27 | 34 |
| | PRURITUS ANI | 1 | | | | | 1 |
| | PSORIASIS AGGRAVATED | | | | | 1 | 1 |
| | PURPURA | | | | | 5 | 5 |
| | RASH | 9 | | | | 26 | 35 |
| | RASH ERYTHEMATOUS | 2 | | | | 6 | 8 |
| | RASH MACULO-PAPULAR | 2 | | | | 2 | 4 |
| | RASH PETECHIAL | | | | | 1 | 1 |
| | RASH PRURITIC | 3 | | | | 21 | 24 |
| | RASH PURPURIC | | | | | 1 | 1 |
| | RASH PUSTULAR | | | | | 2 | 2 |
| | SCAR | | | | | 1 | 1 |
| | SKIN DISCOLOURATION | | | | | 1 | 1 |
| | SKIN DISORDER | 1 | | | | | 1 |
| | SKIN DRY | 1 | | | | | 1 |
| | SKIN EXFOLIATION | | | | | 1 | 1 |
| | SKIN IRRITATION | | | | | 1 | 1 |
| | SKIN NODULE | | | | | 1 | 1 |
| | SKIN ULCERATION | | | | | 1 | 1 |
| | TOXIC EPIDERMAL NECROLYSIS | 1 | | | | | 1 |
| URTICARIA | 5 | | | 1 | 19 | 25 | |
| VESICULAR RASH | | | | | 1 | 1 | |
| *** Total for Group *** | | 55 | | 2 | 179 | 236 | |
| Special Senses | reaction | | | | | | |
| | ANOSMIA | 1 | | | | 4 | 5 |
| | CATARACT | | | | | 1 | 1 |
| | CHROMATOPSIA | 1 | | | | | 1 |
| | CONJUNCTIVITIS | | | | | 4 | 4 |

(Continued)

Statins

| | | Medicine | | | | | Total |
|-------------------------|-----------------------|---------------|--------------|--------------|---------------|--------------|-------|
| | | ATORVAS-TATIN | FLUVAST-ATIN | PRAVAST-ATIN | ROSUVAS-TATIN | SIMVAST-ATIN | |
| | | N | N | N | N | N | |
| RGROUP | reaction | | | | | | |
| Special Senses | DIPLOPIA | | | | | 4 | 4 |
| | DRY EYES | | | | | 1 | 1 |
| | DYSGEUSIA | 1 | | | | 3 | 4 |
| | 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 |
| | PHOTOPHOBIA | 1 | | | | | 1 |
| | TASTE LOSS | 2 | | | | 1 | 3 |
| | TASTE METALLIC | | | | | 4 | 4 |
| | TASTE PERVERSION | 2 | | | | 3 | 5 |
| | TINNITUS | 1 | | 1 | 1 | 4 | 7 |
| | TINNITUS AGGRAVATED | | | | | 1 | 1 |
| | UVEITIS | | | | | 1 | 1 |
| | VISION ABNORMAL | | | | | 8 | 8 |
| | VISION BLURRED | | | | | 8 | 8 |
| | VISION DECREASED | 1 | | | | | 1 |
| XEROPHTHALMIA | | | | | 3 | 3 | |
| *** Total for Group *** | | 11 | | 1 | 1 | 59 | 72 |
| Urinary | reaction | | | | | | |
| | ANURIA | | | | | 1 | 1 |
| | DYSURIA | | | 1 | | 1 | 2 |
| | ENURESIS | | | | | 1 | 1 |
| | HAEMATURIA | | | | | 5 | 5 |
| | HYDRONEPHROSIS | 1 | | | | | 1 |
| | KIDNEY CONTRACTED | | | | | 1 | 1 |
| | MICTURITION DISORDER | | | | | 2 | 2 |
| | MICTURITION FREQUENCY | 2 | | 2 | | 4 | 8 |

(Continued)

Statins

| | | Medicine | | | | | Total |
|-----------------|--------------------------|---------------|--------------|--------------|---------------|--------------|-------|
| | | ATORVAS-TATIN | FLUVAST-ATIN | PRAVAST-ATIN | ROSUVAS-TATIN | SIMVAST-ATIN | |
| | | N | N | N | N | N | |
| RGROUP | reaction | | | | | | |
| Urinary | NOCTURIA | 2 | | | | 2 | 4 |
| | NOCTURIA AGGRAVATED | | | | | 1 | 1 |
| | OLIGURIA | | | | | 2 | 2 |
| | POLYURIA | 1 | | | | | 1 |
| | RENAL FAILURE ACUTE | 1 | | | | 23 | 24 |
| | RENAL FAILURE AGGRAVATED | | | | | 2 | 2 |
| | RENAL FAILURE NOS | | | | | 3 | 3 |
| | RENAL FUNCTION ABNORMAL | 2 | | | | 4 | 6 |
| | RENAL PAIN | | | | | 3 | 3 |
| | RETROPERITONEAL FIBROSIS | 1 | | | | | 1 |
| | URINE ABNORMAL | | | | | 3 | 3 |
| | URINE DISCOLOURATION | 2 | | | | 1 | 3 |
| | URINE ODOUR FOUL | 1 | | | | 1 | 2 |
| | *** Total for Group *** | | 13 | | 3 | | 60 |
| Total Reactions | | 710 | 3 | 14 | 31 | 2696 | 3454 |