



Report Title: Pradaxa (dabigatran)
Spontaneous Reports received by CARM

Prepared for: OIA Request

Prepared by: New Zealand Pharmacovigilance Centre
12 October 2011

Period Covered: This search covers all reports up to 30 September 2011

Summary: This document contains an extract of the 216 reports received by CARM as at 30 September 2011 in response to the OIA request of the same date.

ICH Seriousness: ICH seriousness is assessed in accordance with ICH E2D definitions

- Not serious
- Congenital abnormality
- Died
- Hospitalisation or prolonged hospitalisation
- Life Threatening
- Intervention required to avoid permanent disability
- Persisting disability (*as assessed at the time of the report*)

One report may have more than one reaction described. Seriousness is assessed for each report based on the 'result/outcome of the adverse reaction(s)'; the individual reactions are not separately assessed for seriousness.

Contents: Caveat Document
Report 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

DABIGATRAN - REPORTS received by CARM up to 30/09/2011

| REPORT DATE | REACTIONS | DRUGS | AGE Group | SEX | Patient Outcome | ICH Seriousness |
|-------------|--|--|-----------|-----|----------------------------|------------------|
| MAY2009 | THROMBOSIS VENOUS /DEEP EMBOLISM PULMONARY | * DABIGATRAN | 70 - 79 | M | Unknown outcome | Life threatening |
| AUG2010 | THROMBOEMBOLISM EMBOLISM CEREBRAL | * DABIGATRAN ACETYLSALICYLIC ACID | 60 - 69 | M | Recovered without sequelae | Hospitalisation |
| JUL2011 | DYSPEPSIA | * DABIGATRAN | 70 - 79 | F | Recovered without sequelae | Not Serious |
| JUL2011 | OEDEMA LEGS TIREDNESS | * DABIGATRAN | 80 plus | M | Recovered without sequelae | Not Serious |
| JUL2011 | OEDEMA PERIPHERAL WEIGHT INCREASE PULMONARY OEDEMA | * DABIGATRAN NIFEDIPINE QUINAPRIL BUDESONIDE/EFORMOTEROL FRUSEMIDE | 70 - 79 | F | Unknown outcome | Not Serious |
| JUL2011 | MELAENA MEDICATION ERROR INR INCREASED GI HAEMORRHAGE | * DABIGATRAN * WARFARIN SERETIDE SIMVASTATIN FRUSEMIDE | 80 plus | M | Not yet recovered | Life threatening |

| REPORT DATE | REACTIONS | DRUGS | AGE Group | SEX | Patient Outcome | ICH Seriousness |
|-------------|---|--|-----------|-----|----------------------------|-----------------|
| JUL2011 | CARDIAC ARREST HAEMORRHAGE NOS | * DABIGATRAN WARFARIN | 80 plus | M | Died - unrelated to drug | Died |
| JUL2011 | HAEMORRHAGE SUBDURAL WOUND INFECTION | * DABIGATRAN CILAZAPRIL NITROGLIC ACID WARFARIN BEZAFIBRATE | 80 plus | F | Recovered without sequelae | Intervention |
| JUL2011 | RECTAL BLEEDING MEDICATION ERROR | * DABIGATRAN ACETYLSALICYLIC ACID PARACETAMOL SIMVASTATIN WARFARIN | 80 plus | M | Recovered without sequelae | Hospitalisation |
| JUL2011 | RENAL FAILURE ACUTE CARDIAC FAILURE GINGIVAL BLEEDING MEDICATION ERROR | * DABIGATRAN METOPROLOL PREDNISONO FRUSEMIDE ISOSORBIDE | 80 plus | F | Not yet recovered | Hospitalisation |
| JUL2011 | DYSPNOEA PAROXYSMAL NOCTURNAL | * DABIGATRAN FRUSEMIDE TRAMADOL SIMVASTATIN METOPROLOL | 80 plus | M | Not yet recovered | Not Serious |
| JUL2011 | ABDOMINAL PAIN MEDICATION ERROR | * DABIGATRAN LISINAPRIL ACETYLSALICYLIC ACID FRUSEMIDE | 80 plus | F | Not yet recovered | Not Serious |

| REPORT DATE | REACTIONS | DRUGS | AGE Group | SEX | Patient Outcome | ICH Seriousness |
|-------------|---|--|-----------|-----|-------------------------------|-----------------|
| JUL2011 | RECTAL BLEEDING | * DABIGATRAN METOPROLOL ENALAPRIL FRUSEMIDE DIGOXIN | 70 - 79 | F | Not yet recovered | Not Serious |
| JUL2011 | MELAENA PULMONARY HAEMORRHAGE MEDICATION ERROR INR INCREASED APTT INCREASED | * DABIGATRAN WARFARIN ATORVASTATIN DIGOXIN AMOXICILLIN | 80 plus | M | Died drug may be contributory | Not Serious |
| JUL2011 | MELAENA ANAEMIA | * DABIGATRAN OMEPRAZOLE DILTIAZEM LORATADINE CALCIUM CARBONATE | 80 plus | M | Not yet recovered | Hospitalisation |
| JUL2011 | HALLUCINATION LETHARGY FATIGUE MEDICATION ERROR GASTRIC ULCER | * DABIGATRAN WARFARIN CITALOPRAM SIMVASTATIN OMEPRAZOLE | 80 plus | M | Not yet recovered | Hospitalisation |
| JUL2011 | NAUSEA DYSPEPSIA DIZZINESS | * DABIGATRAN SIMVASTATIN METFORMIN QUETIAPINE FRUSEMIDE | 60 - 69 | F | Recovered without sequelae | Not Serious |
| JUL2011 | HEADACHE COUGHING DIZZINESS DIARRHOEA DYSPNOEA | * DABIGATRAN SIMVASTATIN METOPROLOL NAPROXEN DIGOXIN | 60 - 69 | F | Not yet recovered | Not Serious |

| REPORT DATE | REACTIONS | DRUGS | AGE Group | SEX | Patient Outcome | ICH Seriousness |
|-------------|---|--|-----------|-----|-------------------|------------------|
| JUL2011 | MELAENA INR INCREASED | * DABIGATRAN THYROXINE METOPROLOL TAMOXIFEN WARFARIN | 80 plus | F | Not yet recovered | Life threatening |
| JUL2011 | HAEMATURIA MEDICATION ERROR | * DABIGATRAN WARFARIN | 80 plus | F | Unknown outcome | Hospitalisation |
| JUL2011 | MEDICATION ERROR EPISTAXIS | * DABIGATRAN | 80 plus | F | Unknown outcome | Not Serious |
| JUL2011 | MEDICATION ERROR HAEMORRHAGE RECTUM DIARRHOEA | * DABIGATRAN WARFARIN | 70 - 79 | M | Unknown outcome | Hospitalisation |
| JUL2011 | MEDICATION ERROR HAEMORRHAGE RECTUM | * DABIGATRAN | 80 plus | F | Unknown outcome | Hospitalisation |
| JUL2011 | MELAENA | * DABIGATRAN HYDROCORTISONE AQUEOUS CREAM WARFARIN | 80 plus | M | Not yet recovered | Not Serious |



| REPORT DATE | REACTIONS | DRUGS | AGE Group | SEX | Patient Outcome | ICH Seriousness |
|-------------|--|---|-----------|-----|----------------------------|-----------------|
| JUL2011 | HAEMOPTYSIS RECTAL BLEEDING PURPURA INR INCREASED | * DABIGATRAN ACETYLSALICYLIC ACID IBUPROFEN ALLOPURINOL WARFARIN | 80 plus | M | Not yet recovered | Hospitalisation |
| AUG2011 | DIARRHOEA VOMITING | * DABIGATRAN | 80 plus | F | Recovered without sequelae | Not Serious |
| AUG2011 | PERIPHERAL COLDNESS ARTHRALGIA | * DABIGATRAN | 70 - 79 | F | Not yet recovered | Not Serious |
| AUG2011 | ANKLE OEDEMA DYSPNOEA | * DABIGATRAN FLUOXETINE FRUSEMIDE METOPROLOL CANDESARTAN | 70 - 79 | F | Not yet recovered | Not Serious |
| AUG2011 | DYSPEPSIA NAUSEA VOMITING ABDOMINAL PAIN | * DABIGATRAN FRUSEMIDE OMEPRAZOLE ALENDRONATE + CHOLECALCIFEROL BIMATOPROST | 80 plus | F | Recovered without sequelae | Not Serious |
| AUG2011 | RECTAL BLEEDING MEDICATION ERROR | * DABIGATRAN WARFARIN VERAPAMIL COLOXYL/SENNA FRUSEMIDE | 80 plus | M | Not yet recovered | Not Serious |

| REPORT DATE | REACTIONS | DRUGS | AGE Group | SEX | Patient Outcome | ICH Seriousness |
|-------------|--|---|-----------|-----|----------------------------|-----------------|
| AUG2011 | DYSPEPSIA | * DABIGATRAN | 70 - 79 | M | Recovered without sequelae | Not Serious |
| AUG2011 | RASH | * DABIGATRAN DIGOXIN ACETYLSALICYLIC ACID AMILORIDE/FRUSEMIDE SIMVASTATIN | 70 - 79 | M | Recovered without sequelae | Not Serious |
| AUG2011 | RECTAL BLEEDING | * DABIGATRAN WARFARIN METOPROLOL NORTRIPTYLINE DILTIAZEM | 80 plus | F | Not yet recovered | Hospitalisation |
| AUG2011 | MELAENA | * DABIGATRAN VERAPAMIL SR ATORVASTATIN WARFARIN | 70 - 79 | M | Recovered without sequelae | Not Serious |
| AUG2011 | GASTROESOPHAGEAL REFLUX MELAENA | * DABIGATRAN | 70 - 79 | F | Not yet recovered | Not Serious |
| AUG2011 | ABDOMINAL PAIN RECTAL BLEEDING CEREBRAL INFARCTION | * DABIGATRAN FRUSEMIDE SIMVASTATIN DIGOXIN FELODIPINE | 80 plus | M | Not yet recovered | Not Serious |

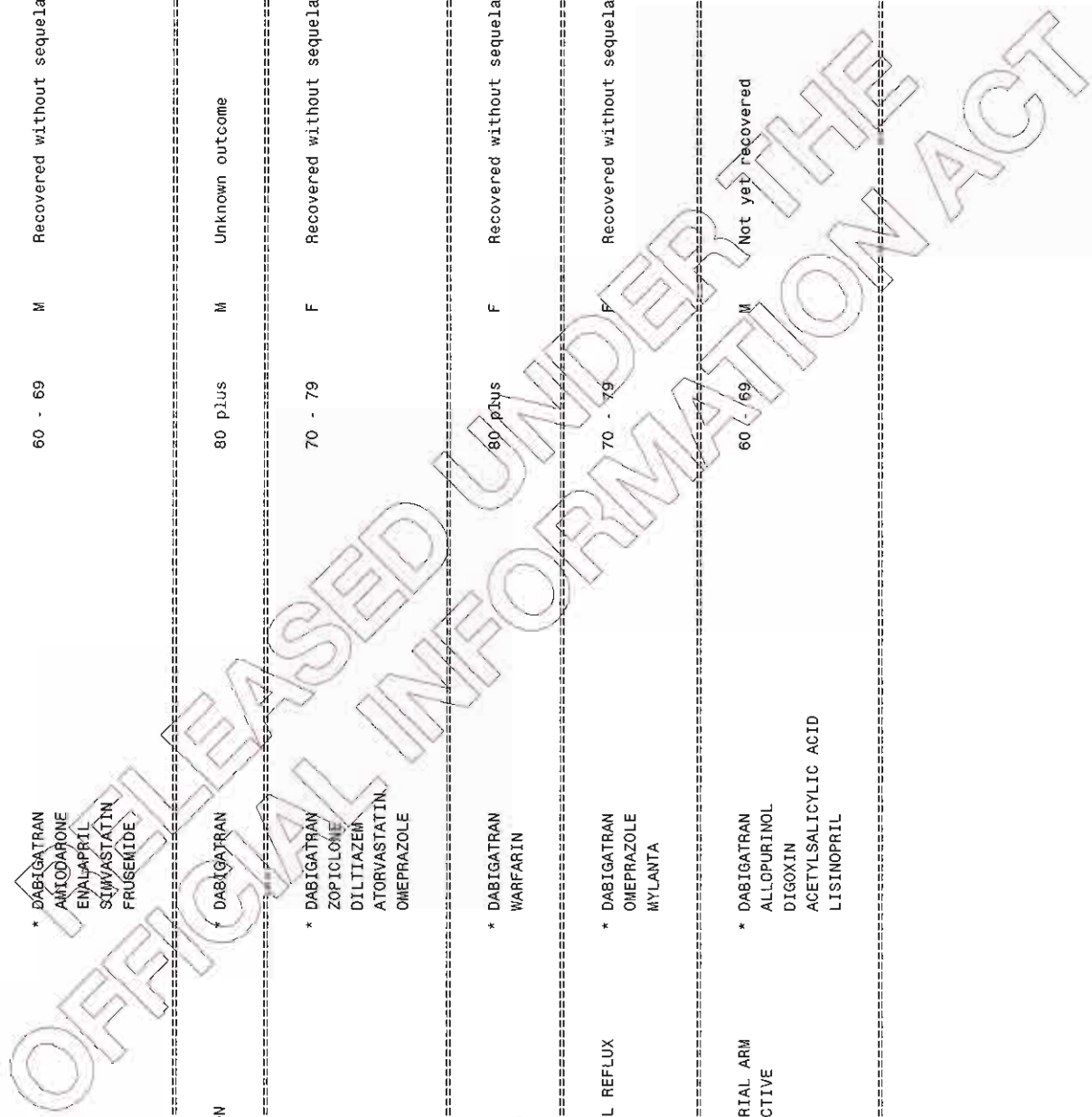
| REPORT DATE | REACTIONS | DRUGS | AGE Group | SEX | Patient Outcome | ICH Seriousness |
|-------------|--|--|-----------|-----|----------------------------|-----------------|
| AUG2011 | URINARY RETENTION FEVER | * DABIGATRAN | Unknown | U | Not yet recovered | Not Serious |
| AUG2011 | NAUSEA RECTAL BLEEDING DIARRHOEA | * DABIGATRAN | Unknown | U | Unknown outcome | Not Serious |
| AUG2011 | URTICARIA | * DABIGATRAN CILAZAPRIL DIGOXIN CARVEDILOL DILTIAZEM | 70 - 79 | M | Recovered without sequelae | Not Serious |
| AUG2011 | CHEST PAIN DYSPHAGIA FLATULENCE DYSPEPSIA | * DABIGATRAN | 60 - 69 | M | Recovered without sequelae | Not Serious |
| AUG2011 | EPISTAXIS HEADACHE DYSPNOEA APATHY DIZZINESS | * DABIGATRAN | 80 plus | M | Recovered without sequelae | Not Serious |
| AUG2011 | HAEMATURIA DIARRHOEA COUGHING | * DABIGATRAN | 70 - 79 | M | Recovered without sequelae | Not Serious |



| REPORT DATE | REACTIONS | DRUGS | AGE Group | SEX | Patient Outcome | ICH Seriousness |
|-------------|---|--|-----------|-----|----------------------------|-----------------|
| AUG2011 | CEREBRAL INFARCTION | * DABIGATRAN WARFARIN ACETYLSALICYLIC ACID | 70 - 79 | F | Died - unrelated to drug | Died |
| AUG2011 | HAEMATURIA | * DABIGATRAN AMOXICILLIN/CLAVULANIC ACID DIGOXIN METOPROLOL LISINAPRIL | 70 - 79 | M | Recovered without sequelae | Hospitalisation |
| AUG2011 | MELAENA CHEST TIGHTNESS DYSPNOEA GASTRIC ULCER | * DABIGATRAN CLOPIDOGREL ACETYLSALICYLIC ACID CILAZAPRIL METFORMIN | 70 - 79 | M | Not yet recovered | Hospitalisation |
| AUG2011 | HAEMATURIA DEPRESSION | * DABIGATRAN | 90 plus | F | Recovered without sequelae | Not Serious |
| AUG2011 | ABDOMINAL PAIN | * DABIGATRAN WARFARIN SIMVASTATIN ALLOPURINOL CLOPIDOGREL | 60 - 69 | M | Not yet recovered | Not Serious |
| AUG2011 | ABDOMINAL PAIN NAUSEA DIARRHOEA | * DABIGATRAN | 60 - 69 | F | Recovered without sequelae | Not Serious |

| REPORT DATE | REACTIONS | DRUGS | AGE Group | SEX | Patient Outcome | ICH Seriousness |
|-------------|---|---|-----------|-----|----------------------------|-----------------|
| AUG2011 | BRADYCARDIA DRUG INTERACTION | DIGOXIN CARVEDILOL DABIGATRAN FRUSEMIDE QUINAPRIL | 60 - 69 | M | Recovered without sequelae | Hospitalisation |
| AUG2011 | DYSPEPSIA | DABIGATRAN | 50 - 59 | F | Unknown outcome | Not Serious |
| AUG2011 | DYSPEPSIA GASTROESOPHAGEAL REFLUX DYSPHAGIA | DABIGATRAN | 70 - 79 | F | Not yet recovered | Not Serious |
| AUG2011 | RECTAL BLEEDING | DABIGATRAN SOTALOL TERAZOSIN SIMVASTATIN BUDESONIDE/EFORMOTEROL | 80 plus | M | Not yet recovered | Not Serious |
| AUG2011 | MELAENA | DABIGATRAN WARFARIN FRUSEMIDE DIGOXIN METOPROLOL | 80 plus | F | Recovered without sequelae | Not Serious |
| AUG2011 | ABDOMINAL PAIN MELAENA | DABIGATRAN WARFARIN METFORMIN CILAZAPRIL ATORVASTATIN | 80 plus | M | Not yet recovered | Not Serious |

| REPORT DATE | REACTIONS | DRUGS | AGE Group | SEX | Patient Outcome | ICH Seriousness |
|-------------|---|--|-----------|-----|----------------------------|-----------------|
| AUG2011 | DYSPEPSIA | * DABIGATRAN AMIODARONE ENALAPRIL SIMVASTATIN FRUSEMIDE | 60 - 69 | M | Recovered without sequelae | Not Serious |
| AUG2011 | BULLOUS ERUPTION | * DABIGATRAN | 80 plus | M | Unknown outcome | Not Serious |
| AUG2011 | OESOPHAGITIS | * DABIGATRAN ZOPICLONE DILTIAZEM ATORVASTATIN OMEPRAZOLE | 70 - 79 | F | Recovered without sequelae | Not Serious |
| AUG2011 | DIARRHOEA RECTAL BLEEDING | * DABIGATRAN WARFARIN | 80 plus | F | Recovered without sequelae | Not Serious |
| AUG2011 | GASTROESOPHAGEAL REFLUX | * DABIGATRAN OMEPRAZOLE MYLANTA | 70 - 79 | F | Recovered without sequelae | Not Serious |
| AUG2011 | THROMBOSIS ARTERIAL ARM MEDICINE INEFFECTIVE | * DABIGATRAN ALLOPURINOL DIGOXIN ACETYLSALICYLIC ACID LISINAPRIL | 60 - 69 | M | Not yet recovered | Hospitalisation |

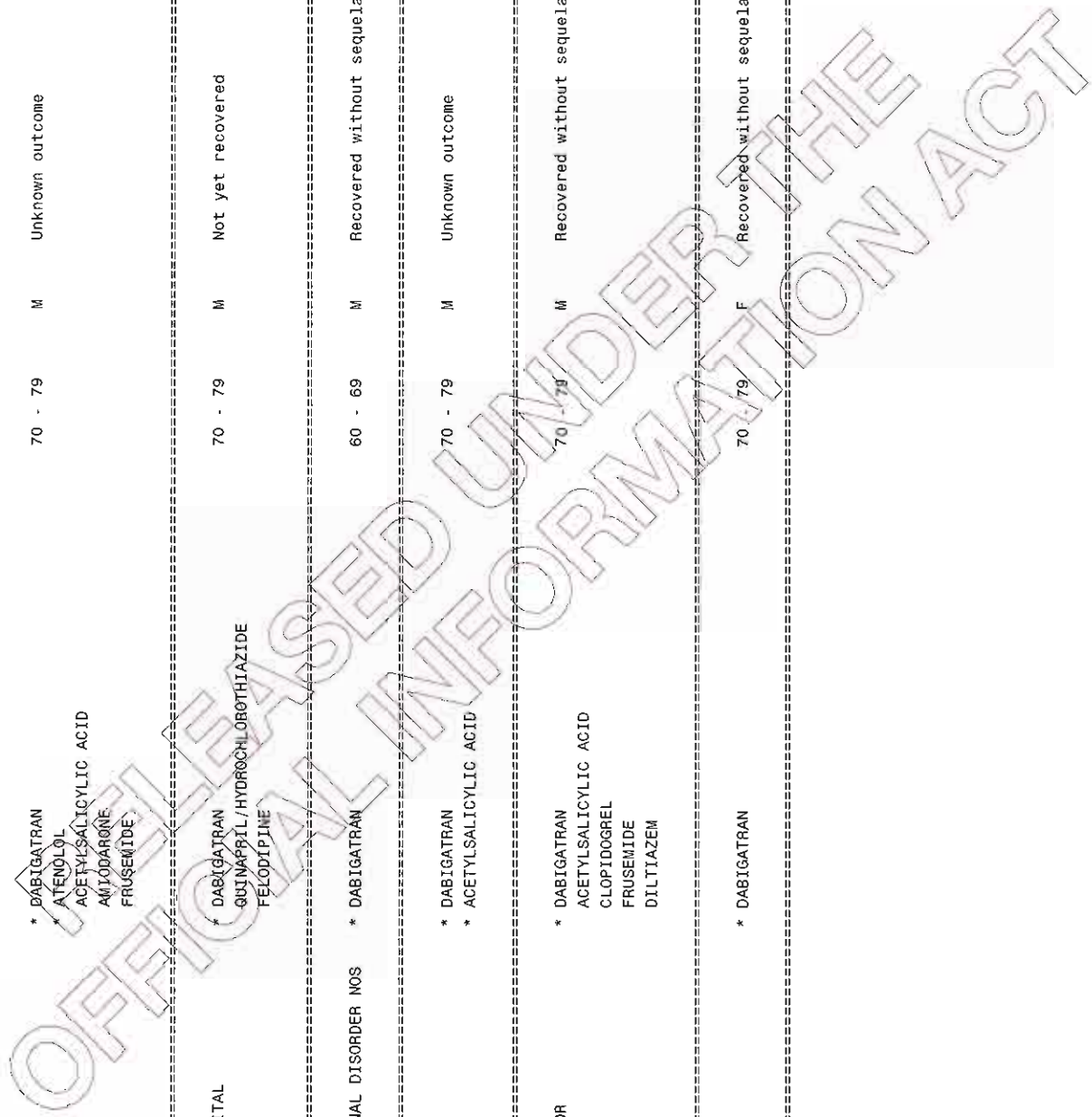


| REPORT DATE | REACTIONS | DRUGS | AGE Group | SEX | Patient Outcome | ICH Seriousness |
|-------------|--|---|-----------|-----|----------------------------|------------------|
| AUG2011 | DYSAESTHESIA PRURITUS | * DABIGATRAN | 60 - 69 | M | Unknown outcome | Not Serious |
| AUG2011 | DYSPHASIA ATAXIA SWEATING INCREASED MYALGIA ABDOMINAL PAIN | DABIGATRAN WARFARIN CARVEDILOL | 70 - 79 | F | Recovered without sequelae | Not Serious |
| AUG2011 | DIARRHOEA NAUSEA ABDOMINAL PAIN MEDICATION ERROR | * DABIGATRAN METOPROLOL BEZAFIBRATE ALENDRONATE + CHOLECALCIFEROL QUINAPRIL | 80 plus | F | Recovered without sequelae | Not Serious |
| AUG2011 | MEDICATION ERROR | * DABIGATRAN WARFARIN | 80 plus | M | Unknown outcome | Life threatening |
| AUG2011 | RECTAL BLEEDING | * DABIGATRAN WARFARIN METOPROLOL SIMVASTATIN DILTIAZEM | 70 - 79 | M | Not yet recovered | Not Serious |
| AUG2011 | DYSPEPSIA DIARRHOEA | * DABIGATRAN | 80 plus | M | Not yet recovered | Not Serious |



| REPORT DATE | REACTIONS | DRUGS | AGE Group | SEX | Patient Outcome | ICH Seriousness |
|-------------|--------------------------------------|---|-----------|-----|----------------------------|------------------|
| AUG2011 | RECTAL BLEEDING | * DABIGATRAN WARFARIN FRUSEMIDE DIGOXIN ALLOPURINOL | 80 plus | F | Not yet recovered | Not Serious |
| AUG2011 | DYSPEPSIA | * DABIGATRAN | 60 - 69 | F | Recovered without sequelae | Not Serious |
| AUG2011 | DYSPEPSIA | * DABIGATRAN CILAZAPRIL METOPROLOL DOTHIEPIN OMEPRAZOLE | 70 - 79 | F | Recovered without sequelae | Not Serious |
| AUG2011 | PURPURA FAECAL INCONTINENCE | * DABIGATRAN CANDESARTAN DILTIAZEM SIMVASTATIN OMEPRAZOLE | 80 plus | M | Recovered without sequelae | Not Serious |
| AUG2011 | INJECTION SITE BLEEDING GASTRITIS | * DABIGATRAN WARFARIN | 80 plus | F | Recovered without sequelae | Not Serious |
| AUG2011 | DIARRHOEA GI HAEMORRHAGE | * DABIGATRAN WARFARIN FLUCLOXACILLIN FRUSEMIDE METOPROLOL | 80 plus | M | Recovered without sequelae | Life threatening |

| REPORT DATE | REACTIONS | DRUGS | AGE Group | SEX | Patient Outcome | ICH Seriousness |
|-------------|-----------------------------------|---|-----------|-----|----------------------------|-----------------|
| AUG2011 | DIARRHOEA LETHARGY HEADACHE | * DABIGATRAN * ATENOLOL * ACETYLSALICYLIC ACID AMIODARONE FRUSEMIDE | 70 - 79 | M | Unknown outcome | Not Serious |
| AUG2011 | OEDEMA PERIORBITAL PRURITUS | * DABIGATRAN QUINAPRIL/HYDROCHLOROTHIAZIDE FELODIPINE | 70 - 79 | M | Not yet recovered | Not Serious |
| AUG2011 | GASTRO- INTESTINAL DISORDER NOS | * DABIGATRAN | 60 - 69 | M | Recovered without sequelae | Not Serious |
| AUG2011 | HAEMATURIA | * DABIGATRAN * ACETYLSALICYLIC ACID | 70 - 79 | M | Unknown outcome | Not Serious |
| AUG2011 | MEDICATION ERROR | * DABIGATRAN ACETYLSALICYLIC ACID CLOPIDOGREL FRUSEMIDE DILTIAZEM | 70 - 79 | M | Recovered without sequelae | Not Serious |
| AUG2011 | DYSPEPSIA | * DABIGATRAN | 70 - 79 | F | Recovered without sequelae | Hospitalisation |



| REPORT DATE | REACTIONS | DRUGS | AGE Group | SEX | Patient Outcome | ICH Seriousness |
|-------------|---|--|-----------|-----|----------------------------|-----------------|
| AUG2011 | DIARRHOEA | * DABIGATRAN ETORICOXIB DILTIAZEM MOXOLOBEMIDE GLIPIZIDE | 60 - 69 | F | Recovered without sequelae | Not Serious |
| AUG2011 | RASH ATAXIA FALL | DABIGATRAN METOPROLOL OXAZEPAM ACETYLSALICYLIC ACID BENDROFLUAZIDE | 80 plus | M | Not yet recovered | Not Serious |
| AUG2011 | ARTHRALGIA MYALGIA CHEST PAIN NAUSEA | * DABIGATRAN SIMVASTATIN FRUSEMIDE METOPROLOL LOSARTAN | 50 - 59 | F | Not yet recovered | Hospitalisation |
| AUG2011 | MACULAR RASH URTICARIA | * DABIGATRAN WARFARIN ROXITHROMYCIN OMEPRAZOLE CITALOPRAM | 70 - 79 | F | Recovered without sequelae | Not Serious |
| AUG2011 | RASH PRURITIC | * DABIGATRAN | 80 plus | F | Not yet recovered | Not Serious |
| AUG2011 | RECTAL BLEEDING | * DABIGATRAN WARFARIN | 80 plus | F | Recovered without sequelae | Not Serious |

| REPORT DATE | REACTIONS | DRUGS | AGE Group | SEX | Patient Outcome | ICH Seriousness |
|-------------|--|---|-----------|-----|----------------------------|-----------------|
| AUG2011 | RECTAL BLEEDING | * DABIGATRAN | 80 plus | F | Recovered without sequelae | Not Serious |
| AUG2011 | RECTAL BLEEDING | * DABIGATRAN METOPROLOL CLONAZEPAM WARFARIN | 70 - 79 | F | Not yet recovered | Not Serious |
| AUG2011 | ORAL PAIN HEADACHE | * DABIGATRAN SOTALOL DIGOXIN BENDROFLUAZIDE OMEPRAZOLE | 70 - 79 | F | Recovered without sequelae | Not Serious |
| AUG2011 | GASTRITIS | * DABIGATRAN | 70 - 79 | M | Not yet recovered | Not Serious |
| AUG2011 | HAEMARTHROSIS MYOCARDIAL INFARCTION | * DABIGATRAN PROPRANOLOL CARBIMAZOLE RANITIDINE | 70 - 79 | F | Not yet recovered | Hospitalisation |
| AUG2011 | RECTAL BLEEDING | * DABIGATRAN METOPROLOL OMEPRAZOLE ISOSORBIDE FRUSEMIDE | 80 plus | F | Not yet recovered | Not Serious |

| REPORT DATE | REACTIONS | DRUGS | AGE Group | SEX | Patient Outcome | ICH Seriousness |
|-------------|---|--|-----------|-----|----------------------------|-----------------|
| AUG2011 | GASTROESOPHAGEAL REFLUX | * DABIGATRAN WARFARIN OMEFRAZOLE CODÉINE THYROXINE | 70 - 79 | F | Recovered without sequelae | Not Serious |
| AUG2011 | VENOUS THROMBOSIS | * DABIGATRAN WARFARIN | 60 - 69 | M | Not yet recovered | Not Serious |
| AUG2011 | DYSPEPSIA | * DABIGATRAN METOPROLOL ATORVASTATIN SILDENAFIL | 50 - 59 | M | Unknown outcome | Not Serious |
| AUG2011 | DYSPEPSIA | * DABIGATRAN CILAZAPRIL FRUSEMIDE METOPROLOL DOXAZOSIN | 80 plus | M | Recovered without sequelae | Not Serious |
| AUG2011 | ABDOMINAL PAIN | * DABIGATRAN | 80 plus | M | Not yet recovered | Not Serious |
| AUG2011 | DIARRHOEA RECTAL BLEEDING HAEMOPTYSIS | * DABIGATRAN WARFARIN SIMVASTATIN DIGOXIN DILTIAZEM | 60 - 89 | F | Recovered without sequelae | Not Serious |

| REPORT DATE | REACTIONS | DRUGS | AGE Group | SEX | Patient Outcome | ICH Seriousness |
|-------------|---|--|-----------|-----|----------------------------|-----------------|
| AUG2011 | MELAENA RECTAL BLEEDING ANAEMIA | * DABIGATRAN WARFARIN ACETYSALICYLIC ACID LANOPRAZOLE DIOXIN | 70 - 79 | M | Not yet recovered | Hospitalisation |
| AUG2011 | HAEMOPTYSIS | * DABIGATRAN BISOPROLOL ACETYSALICYLIC ACID | 70 - 79 | F | Recovered without sequelae | Not Serious |
| AUG2011 | DYSPEPSIA RECTAL BLEEDING | * DABIGATRAN | 80 plus | F | Recovered without sequelae | Not Serious |
| AUG2011 | SKIN DISCOLOURATION PERIPHERAL ISCHAEMIA | * DABIGATRAN | 70 - 79 | M | Not yet recovered | Not Serious |
| AUG2011 | DYSPEPSIA | * DABIGATRAN | 80 plus | M | Recovered without sequelae | Not Serious |
| AUG2011 | DYSPHAGIA CHEST PAIN | * DABIGATRAN | 80 plus | M | Recovered without sequelae | Hospitalisation |

| REPORT DATE | REACTIONS | DRUGS | AGE Group | SEX | Patient Outcome | ICH Seriousness |
|-------------|--|---|-----------|-----|----------------------------|------------------|
| AUG2011 | ABDOMINAL PAIN VOMITING HEADACHE | * DABIGATRAN | 50 - 59 | M | Unknown outcome | Hospitalisation |
| AUG2011 | RECTAL BLEEDING | * DABIGATRAN ACETYSALICYLIC ACID HEPARIN LOW ENOXAPARIN | 80 plus | F | Unknown outcome | Not Serious |
| AUG2011 | PULMONARY HAEMORRHAGE | * DABIGATRAN | Unknown | M | Unknown outcome | Life threatening |
| AUG2011 | RECTAL BLEEDING ANAEMIA | * DABIGATRAN WARFARIN ALENDRONATE + CHOLECALCIFEROL NORTRIPTYLINE DILTIAZEM | 80 plus | F | Recovered without sequelae | Hospitalisation |
| AUG2011 | CONFUSION EMBOLISM CEREBRAL | * DABIGATRAN WARFARIN | Unknown | F | Died - cause unknown | Died |
| AUG2011 | DYSPNOEA CARDIAC FAILURE | * DABIGATRAN | 80 plus | F | Unknown outcome | Hospitalisation |

OFFICIAL INFORMATION ACT

| REPORT DATE | REACTIONS | DRUGS | AGE Group | SEX | Patient Outcome | ICH Seriousness |
|-------------|--|---|-----------|-----|----------------------------|------------------|
| AUG2011 | FALL FRACTURE HAEMORRHAGE SUBDURAL | * DABIGATRAN WARFARIN ACETYLSALICYLIC ACID | 60 - 69 | F | Unknown outcome | Hospitalisation |
| AUG2011 | GASTRIC ULCER GI HAEMORRHAGE | * DABIGATRAN | 80 plus | U | Unknown outcome | Not Serious |
| SEP2011 | RECTAL BLEEDING | * DABIGATRAN DILTIAZEM ATORVASTATIN QUINAPRIL FRUSEMIDE | 60 - 69 | M | Recovered without sequelae | Not Serious |
| SEP2011 | HAEMOPTYSIS DYSPNOEA | * DABIGATRAN FRUSEMIDE QUINAPRIL ISOSORBIDE METOPROLOL | 80 plus | F | Recovered without sequelae | Life threatening |
| SEP2011 | DIZZINESS | * DABIGATRAN DILTIAZEM SALBUTAMOL CHOLECALCIFEROL PARACETAMOL | 60 - 69 | F | Unknown outcome | Not Serious |
| SEP2011 | GASTRO-INTESTINAL DISORDER NOS | * DABIGATRAN SIMVASTATIN METFORMIN ALLOPURINOL DILTIAZEM | 60 - 69 | F | Unknown outcome | Not Serious |

| REPORT DATE | REACTIONS | DRUGS | AGE Group | SEX | Patient Outcome | ICH Seriousness |
|-------------|---|--|-----------|-----|----------------------------|-----------------|
| SEP2011 | RECTAL BLEEDING | * DABIGATRAN WARFARIN SIMVASTATIN FELODIPINE ALENDRONATE + CHOLECALCIFEROL | 80 plus | F | Not yet recovered | Hospitalisation |
| SEP2011 | BNP ABNORMAL | * DABIGATRAN CARVEDILOL CALCIFEROL SIMVASTATIN | 80 plus | F | Not yet recovered | Not Serious |
| SEP2011 | RECTAL BLEEDING GASTRO-INTESTINAL DISORDER NOS | * DABIGATRAN WARFARIN | 80 plus | M | Unknown outcome | Not Serious |
| SEP2011 | DYSPEPSIA | * DABIGATRAN METOPROLOL CILAZAPRIL QUININE | 70 - 79 | F | Recovered without sequelae | Not Serious |
| SEP2011 | DYSPEPSIA GASTROESOPHAGEAL REFLUX | * DABIGATRAN BENDROFLUAZIDE METOPROLOL QUINAPRIL DOXAZOSIN | 70 - 79 | M | Not yet recovered | Not Serious |
| SEP2011 | OEDEMA PHARYNX DYSPEPSIA | * DABIGATRAN | 70 - 79 | M | Not yet recovered | Not Serious |

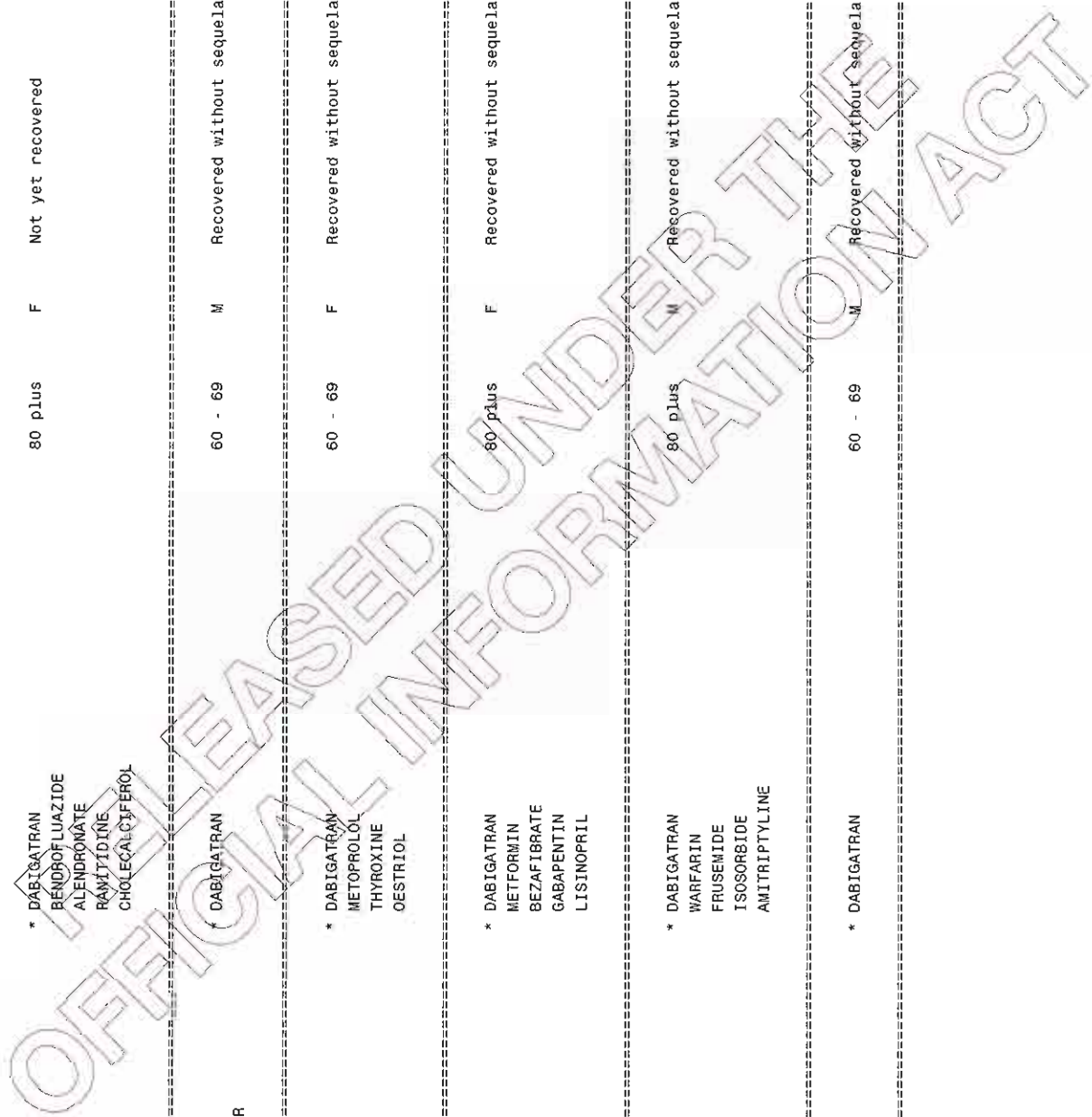
| REPORT DATE | REACTIONS | DRUGS | AGE Group | SEX | Patient Outcome | ICH Seriousness |
|-------------|--|--|-----------|-----|----------------------------|-----------------|
| SEP2011 | RECTAL BLEEDING | * DABIGATRAN WARFARIN SIMVASTATIN OMEPRAZOLE AMITRIPTYLINE | 60 - 69 | M | Unknown outcome | Not Serious |
| SEP2011 | RECTAL BLEEDING | * DABIGATRAN WARFARIN | 50 - 59 | M | Recovered without sequelae | Hospitalisation |
| SEP2011 | MEDICINE INEFFECTIVE HYPERTENSION AGGRAVATED PNEUMONIA | * DABIGATRAN SIMVASTATIN FELODIPINE FINASTERIDE METFORMIN | 70 - 79 | M | Not yet recovered | Hospitalisation |
| SEP2011 | MYALGIA ARTHRALGIA FEELING COLD | * DABIGATRAN AMIODARONE VERAPAMIL SR OMEPRAZOLE | 60 - 69 | M | Recovered without sequelae | Not Serious |
| SEP2011 | HAEMATURIA | * DABIGATRAN DIGOXIN WARFARIN THYROXINE INSULIN ASPART | 80 plus | M | Recovered without sequelae | Not Serious |
| SEP2011 | PHARYNGITIS SHAKING | * DABIGATRAN WARFARIN FLUTICASON FRUSEMIDE SIMVASTATIN | 60 - 69 | F | Recovered without sequelae | Not Serious |

| REPORT DATE | REACTIONS | DRUGS | AGE Group | SEX | Patient Outcome | ICH Seriousness |
|-------------|-------------------------|--|-----------|-----|----------------------------|-----------------|
| SEP2011 | GASTROESOPHAGEAL REFLUX | * DABIGATRAN | 70 - 79 | F | Recovered without sequelae | Not Serious |
| SEP2011 | ABDOMINAL PAIN | * DABIGATRAN CILAZAPRIL INSULIN LISPRO SOTALOL SIMVASTATIN | 60 - 69 | M | Recovered without sequelae | Not Serious |
| SEP2011 | HAEMATURIA | * DABIGATRAN ACETYLSALICYLIC ACID SIMVASTATIN OMEPRAZOLE METOPROLOL | 70 - 79 | F | Recovered without sequelae | Not Serious |
| SEP2011 | DYSPEPSIA | * DABIGATRAN BENDROFLUAZIDE METOPROLOL ETIDRONATE DISODIUM SIMVASTATIN | 60 - 69 | F | Recovered without sequelae | Not Serious |
| SEP2011 | DYSPEPSIA | * DABIGATRAN SIMVASTATIN FRUSEMIDE METFORMIN DIGOXIN | 60 - 69 | F | Not yet recovered | Not Serious |
| SEP2011 | DYSPEPSIA | * DABIGATRAN | 80 plus | F | Recovered without sequelae | Not Serious |

| REPORT DATE | REACTIONS | DRUGS | AGE Group | SEX | Patient Outcome | ICH Seriousness |
|-------------|---|--|-----------|-----|----------------------------|-----------------|
| SEP2011 | EMBOLISM MESENTERIC MEDICINE INEFFECTIVE | * DABIGATRAN DILTIAZEM SIMVASTATIN DIOLOFENAC METOPROLOL | 80 plus | M | Recovered without sequelae | Hospitalisation |
| SEP2011 | RHINITIS HOARSENESS PRURITUS ERYTHEMA DIARRHOEA | * DABIGATRAN LOSARTAN ALLOPURINOL ATORVASTATIN DIGOXIN | 60 - 69 | M | Recovered without sequelae | Not Serious |
| SEP2011 | DYSPEPSIA | * DABIGATRAN SIMVASTATIN OMEPRAZOLE QUINAPRIL SOTALOL | 60 - 69 | M | Recovered without sequelae | Not Serious |
| SEP2011 | DYSPEPSIA CHEST PAIN | * DABIGATRAN ATORVASTATIN SALBUTAMOL FRUSEMIDE CILAZAPRIL | 70 - 79 | M | Not yet recovered | Not Serious |
| SEP2011 | DYSPEPSIA | * DABIGATRAN SIMVASTATIN QUINAPRIL OMEPRAZOLE FRUSEMIDE | 60 - 69 | M | Unknown outcome | Not Serious |
| SEP2011 | GASTROESOPHAGEAL REFLUX | * DABIGATRAN METFORMIN METOPROLOL ACETYLSALICYLIC ACID ALLOPURINOL | 70 - 79 | M | Recovered without sequelae | Not Serious |

| REPORT DATE | REACTIONS | DRUGS | AGE Group | SEX | Patient Outcome | ICH Seriousness |
|-------------|--|---|-----------|-----|----------------------------|-----------------|
| SEP2011 | DYSPEPSIA BLEEDING TIME INCREASED HEALING IMPAIRED | * DABIGATRAN WARFARIN METOPROLOL ATORVASTATIN CELECOXIB | 70 - 79 | M | Not yet recovered | Not Serious |
| SEP2011 | DYSPEPSIA | * DABIGATRAN | 70 - 79 | F | Recovered without sequelae | Not Serious |
| SEP2011 | PURPURA ARRHYTHMIA APTT INCREASED HYPOKALAEMIA RENAL FAILURE NOS | * DABIGATRAN CILAZAPRIL FRUSEMIDE DIGOXIN WARFARIN | 80 plus | F | Died - unrelated to drug | Died |
| SEP2011 | MEDICATION ERROR | * DABIGATRAN DIGOXIN COMBIVENT METOPROLOL OMEPRAZOLE | 80 plus | F | Recovered without sequelae | Not Serious |
| SEP2011 | GASTROESOPHAGEAL REFLUX NAUSEA DIARRHOEA | * DABIGATRAN ATORVASTATIN OMEPRAZOLE METOPROLOL DILTIAZEM | 80 - 89 | F | Recovered without sequelae | Not Serious |
| SEP2011 | MEDICATION ERROR | * DABIGATRAN | 80 plus | M | Unknown outcome | Not Serious |

| REPORT DATE | REACTIONS | DRUGS | AGE Group | SEX | Patient Outcome | ICH Seriousness |
|-------------|-------------------------------|---|-----------|-----|----------------------------|-----------------|
| SEP2011 | DYSPEPSIA | * DABIGATRAN BENDROFLUAZIDE ALENDRONATE RAMITRIDINE CHOLECALCIFEROL | 80 plus | F | Not yet recovered | Not Serious |
| SEP2011 | DYSPEPSIA MEDICATION ERROR | * DABIGATRAN | 60 - 69 | M | Recovered without sequelae | Not Serious |
| SEP2011 | DYSPEPSIA | * DABIGATRAN METOPROLOL THYROXINE OESTRIOL | 60 - 69 | F | Recovered without sequelae | Not Serious |
| SEP2011 | DYSPEPSIA | * DABIGATRAN METFORMIN BEZAFIBRATE GABAPENTIN LISINAPRIL | 80 plus | F | Recovered without sequelae | Not Serious |
| SEP2011 | MELAEMA HAEMATURIA | * DABIGATRAN WARFARIN FRUSEMIDE ISOSORBIDE AMITRIPTYLINE | 80 plus | M | Recovered without sequelae | Not Serious |
| SEP2011 | DYSPEPSIA | * DABIGATRAN | 60 - 69 | M | Recovered without sequelae | Not Serious |



| REPORT DATE | REACTIONS | DRUGS | AGE Group | SEX | Patient Outcome | ICH Seriousness |
|-------------|---|--|-----------|-----|----------------------------|-----------------|
| SEP2011 | DYSPEPSIA DRUG INTERACTION PROSTATIC DISORDER HAEMATURIA | I DABIGATRAN I FRUSEMIDE ALLOPURINOL SIMVASTATIN DILTIAZEM | 70 - 79 | M | Recovered without sequelae | Not Serious |
| SEP2011 | GINGIVAL BLEEDING | * DABIGATRAN WARFARIN | 60 - 69 | M | Recovered without sequelae | Not Serious |
| SEP2011 | MELAENA CHEST PAIN DYSPEPSIA GASTRITIS | * DABIGATRAN WARFARIN SIMVASTATIN PAROXETINE FRUSEMIDE | 80 plus | F | Recovered without sequelae | Not Serious |
| SEP2011 | HAEMATURIA | * DABIGATRAN METOPROLOL AMITRIPTYLINE WARFARIN | 80 plus | M | Recovered without sequelae | Not Serious |
| SEP2011 | DYSPEPSIA DIARRHOEA HEADACHE MYALGIA | * DABIGATRAN PAROXETINE ISOSORBIDE METOPROLOL | 40 - 49 | F | Not yet recovered | Not Serious |
| SEP2011 | RECTAL BLEEDING | * DABIGATRAN WARFARIN | 70 - 79 | F | Not yet recovered | Not Serious |

| REPORT DATE | REACTIONS | DRUGS | AGE Group | SEX | Patient Outcome | ICH Seriousness |
|-------------|--|---|-----------|-----|----------------------------|-----------------------|
| SEP2011 | GASTRIC ULCER GI HAEMORRHAGE | * DABIGATRAN | 70 - 79 | F | Unknown outcome | Hospitalisation |
| SEP2011 | HYPONATRAEMIA BRADYCARDIA DRUG INTERACTION | * DABIGATRAN * ATENOLOL DOXAZOSIN INFLUENZA VIRUS VACCINE INACT. | 80 plus | M | Recovered without sequelae | Hospitalisation |
| SEP2011 | THROMBOSIS CEREBRAL | * DABIGATRAN METFORMIN SIMVASTATIN METOPROLOL WARFARIN | 70 - 79 | M | Recovered without sequelae | Life threatening |
| SEP2011 | HAEMORRHAGE SUBDURAL PARALYSIS | * DABIGATRAN WARFARIN | 80 plus | F | Recovered with sequelae | Persisting Disability |
| SEP2011 | MELAENA | * DABIGATRAN | Unknown | M | Not yet recovered | Hospitalisation |
| SEP2011 | HAEMATURIA | * DABIGATRAN BENDROFLUAZIDE DILTIAZEM | 80 plus | M | Recovered without sequelae | Hospitalisation |



| REPORT DATE | REACTIONS | DRUGS | AGE Group | SEX | Patient Outcome | ICH Seriousness |
|-------------|--|--|-----------|-----|----------------------------|-----------------|
| SEP2011 | FALL HAEMATOMA FRACTURE PATHOLOGICAL | * DABIGATRAN | Unknown | F | Unknown outcome | Hospitalisation |
| SEP2011 | HAEMATURIA | * DABIGATRAN WARFARIN | Unknown | M | Unknown outcome | Hospitalisation |
| SEP2011 | DYSPEPSIA CHEST PAIN | * DABIGATRAN WARFARIN | 80 plus | F | Recovered without sequelae | Hospitalisation |
| SEP2011 | DYSPEPSIA | * DABIGATRAN WARFARIN PANTOPRAZOLE VALPROATE SODIUM CILAZAPRIL | 80 plus | F | Recovered without sequelae | Not Serious |
| SEP2011 | FALL EPISTAXIS | * DABIGATRAN | Unknown | F | Unknown outcome | Hospitalisation |
| SEP2011 | RECTAL BLEEDING | * DABIGATRAN WARFARIN FRUSEMIDE NORTRIPTYLINE METOPROLOL | 80 plus | F | Unknown outcome | Hospitalisation |

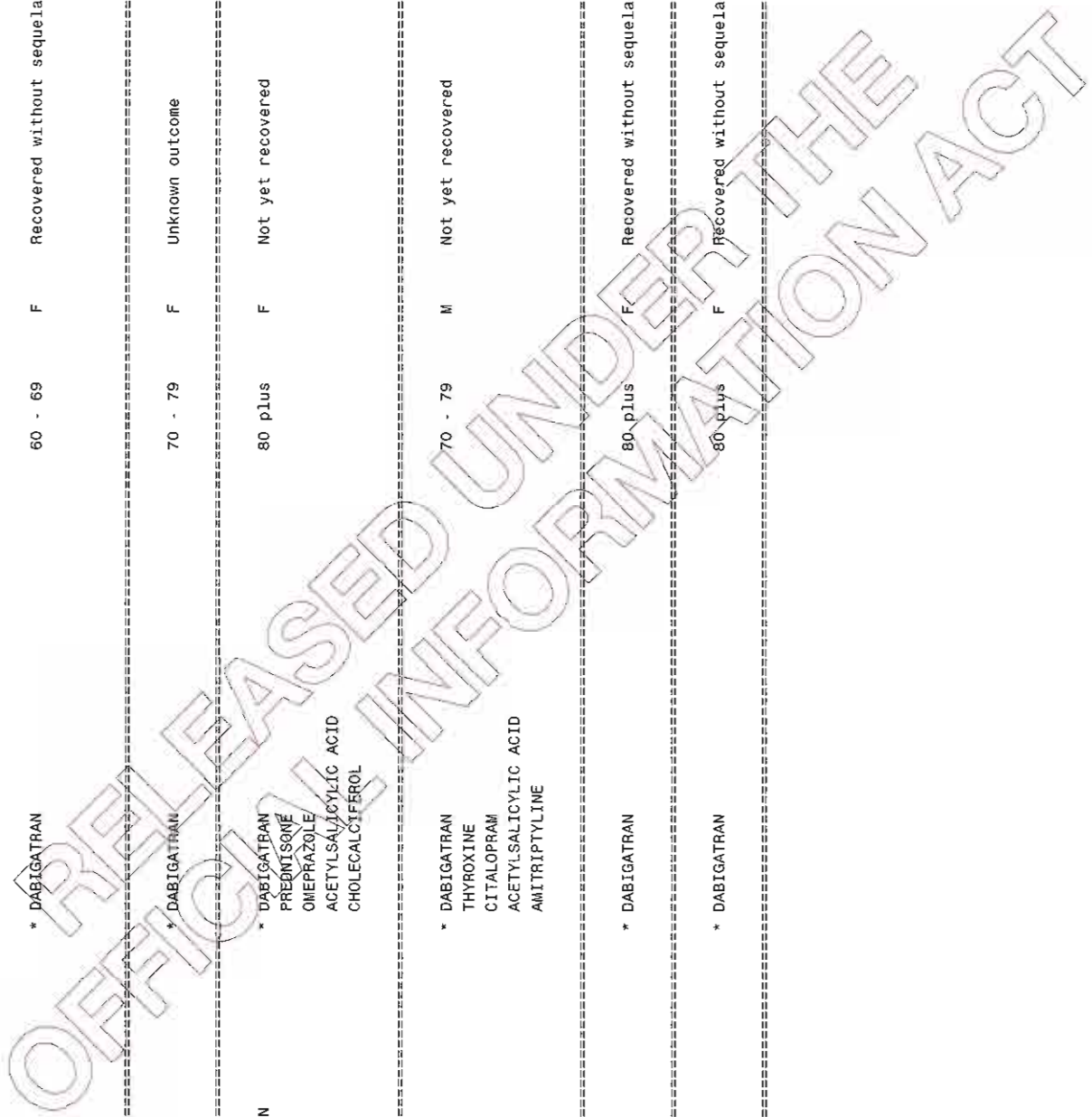
DABIGATRAN - REPORTS received by CARM up to 30/09/2011

| REPORT DATE | REACTIONS | DRUGS | AGE Group | SEX | Patient Outcome | ICH Seriousness |
|-------------|---|---|-----------|-----|-------------------------------|------------------|
| SEP2011 | GI HAEMORRHAGE | * DABIGATRAN | 60 - 69 | M | Unknown outcome | Hospitalisation |
| SEP2011 | CEREBRAL ISCHAEMIA | * DABIGATRAN * WARFARIN | 80 plus | F | Unknown outcome | Life threatening |
| SEP2011 | ABDOMINAL PAIN MELAENA | * DABIGATRAN | 70 - 79 | M | Not yet recovered | Hospitalisation |
| SEP2011 | GI HAEMORRHAGE | * DABIGATRAN | 70 - 79 | F | Unknown outcome | Hospitalisation |
| SEP2011 | GINGIVAL BLEEDING MELAENA GI HAEMORRHAGE CARDIAC FAILURE | * DABIGATRAN | 80 plus | F | Died drug may be contributory | Died |
| SEP2011 | BNP ABNORMAL | * DABIGATRAN ATORVASTATIN THYROXINE METOPROLOL VERAPAMIL SR | 70 - 79 | M | Unknown outcome | Not Serious |



| REPORT DATE | REACTIONS | DRUGS | AGE Group | SEX | Patient Outcome | ICH Seriousness |
|-------------|--|---|-----------|-----|----------------------------|-----------------|
| SEP2011 | DIARRHOEA CONSTIPATION DIZZINESS LETHARGY | * DABIGATRAN SIMVASTATIN PANTOPRAZOLE QUINAPRIL FRUSEMIDE | 80 plus | F | Not yet recovered | Not Serious |
| SEP2011 | RECTAL BLEEDING DIARRHOEA MALAISE | * DABIGATRAN DOXAZOSIN CILAZAPRIL FELODIPINE ACETYLSALICYLIC ACID | 80 plus | M | Recovered without sequelae | Not Serious |
| SEP2011 | GI HAEMORRHAGE EMBOLISM PULMONARY MEDICATION ERROR | * DABIGATRAN WARFARIN ATORVASTATIN CILAZAPRIL METOPROLOL | 70 - 79 | M | Recovered without sequelae | Hospitalisation |
| SEP2011 | EPISTAXIS | * DABIGATRAN CILAZAPRIL METOPROLOL FRUSEMIDE WARFARIN | 80 plus | M | Recovered without sequelae | Not Serious |
| SEP2011 | TIREDFNESS DYSPHAGIA TONGUE OEDEMA DYSPEPSIA DYSPONOEA | * DABIGATRAN DILTIAZEM | 80 plus | F | Not yet recovered | Not Serious |
| SEP2011 | DYSPEPSIA | * DABIGATRAN DIGOXIN METOPROLOL | 70 - 79 | M | Recovered without sequelae | Not Serious |

| REPORT DATE | REACTIONS | DRUGS | AGE Group | SEX | Patient Outcome | ICH Seriousness |
|-------------|--|---|-----------|-----|----------------------------|-----------------|
| SEP2011 | HEADACHE DYSPEPSIA SOMNOLENCE | * DABIGATRAN | 60 - 69 | F | Recovered without sequelae | Not Serious |
| SEP2011 | RASH PETECHIAL | * DABIGATRAN | 70 - 79 | F | Unknown outcome | Not Serious |
| SEP2011 | NASAL CONGESTION BRONCHOSPASM DYSPNOEA HEADACHE | * DABIGATRAN PREDNISONÉ OMEPRAZOLE ACETYLSALICYLIC ACID CHOLECALCIFEROL | 80 plus | F | Not yet recovered | Not Serious |
| SEP2011 | DYSPEPSIA DYSPHAGIA | * DABIGATRAN THYROXINE CITALOPRAM ACETYLSALICYLIC ACID AMITRIPTYLINE | 70 - 79 | M | Not yet recovered | Not Serious |
| SEP2011 | LEG PAIN | * DABIGATRAN | 80 plus | F | Recovered without sequelae | Not Serious |
| SEP2011 | DYSPEPSIA | * DABIGATRAN | 80 plus | F | Recovered without sequelae | Not Serious |



| REPORT DATE | REACTIONS | DRUGS | AGE Group | SEX | Patient Outcome | ICH Seriousness |
|-------------|--------------------------------------|--|-----------|-----|----------------------------|-----------------|
| SEP2011 | DYSPEPSIA GASTROESOPHAGEAL REFLUX | * DABIGATRAN ALLOPURINOL FRUSEMIDE CILAZAPRIL THYROXINE | 80 plus | F | Recovered without sequelae | Not Serious |
| SEP2011 | OESOPHAGITIS | * DABIGATRAN SIMVASTATIN FLUTICASON FRUSEMIDE OMEPRazole | 80 plus | F | Recovered without sequelae | Hospitalisation |
| SEP2011 | GASTROESOPHAGEAL REFLUX DYSPEPSIA | * DABIGATRAN OMEPRazole AMLODIPINE METOPROLOL | 60 - 69 | F | Not yet recovered | Not Serious |
| SEP2011 | GI HAEMORRHAGE | * DABIGATRAN | 80 plus | M | Recovered without sequelae | Not Serious |
| SEP2011 | ABDOMINAL PAIN | * DABIGATRAN THYROXINE SIMVASTATIN CILAZAPRIL METOPROLOL | 50 - 59 | F | Recovered without sequelae | Not Serious |
| SEP2011 | DYSPEPSIA | * DABIGATRAN ALLOPURINOL EZETIMIBE DIGOXIN METOPROLOL | 80 plus | M | Recovered without sequelae | Not Serious |

| REPORT DATE | REACTIONS | DRUGS | AGE Group | SEX | Patient Outcome | ICH Seriousness |
|-------------|---|---|-----------|-----|----------------------------|-----------------|
| SEP2011 | CONFUSION SLEEP DISTURBED | * DABIGATRAN METFORMIN SALBUTAMOL LISINOPRIL FRUSEMIDE | 60 - 69 | F | Recovered without sequelae | Not Serious |
| SEP2011 | CONFUSION | * DABIGATRAN BIGOXIN METOPROLOL PANTOPRAZOLE FRUSEMIDE | 80 plus | M | Not yet recovered | Not Serious |
| SEP2011 | DYSPEPSIA | * DABIGATRAN | 80 plus | F | Recovered without sequelae | Not Serious |
| SEP2011 | GI HAEMORRHAGE | * DABIGATRAN SIMVASTATIN GLYCERYL TRINITRATE DIGOXIN PROCHLORPERAZINE | 80 plus | M | Not yet recovered | Not Serious |
| SEP2011 | DYSPNOEA FATIGUE MELAENA ANAEMIA | * DABIGATRAN | 70 - 79 | M | Recovered without sequelae | Hospitalisation |
| SEP2011 | ACNE DIARRHOEA | * DABIGATRAN ACETYLSALICYLIC ACID | 70 - 79 | M | Recovered without sequelae | Not Serious |

| REPORT DATE | REACTIONS | DRUGS | AGE Group | SEX | Patient Outcome | ICH Seriousness |
|-------------|---|---|-----------|-----|----------------------------|------------------|
| SEP2011 | EPISTAXIS HEADACHE MELAENA | * DABIGATRAN METOPROLOL DIGOXIN | 70 - 79 | F | Not yet recovered | Not Serious |
| SEP2011 | GI HAEMORRHAGE EPISTAXIS PEPTIC ULCER | * DABIGATRAN WARFARIN SIMVASTATIN FRUSEMIDE BICALUTAMIDE | 70 - 79 | M | Recovered without sequelae | Hospitalisation |
| SEP2011 | MELAENA VOMITING HAEMATEMESIS | * DABIGATRAN CHOLECALCIFEROL FRUSEMIDE DICLOFENAC CEPHALEXIN | 80 plus | F | Not yet recovered | Hospitalisation |
| SEP2011 | RECTAL BLEEDING | * DABIGATRAN METOPROLOL BENDROFLUAZIDE AMLODIPINE SIMVASTATIN | 60 - 69 | M | Not yet recovered | Not Serious |
| SEP2011 | MYOCARDIAL INFARCTION | * DABIGATRAN ATENOLOL METFORMIN ATORVASTATIN CANDESARTAN | 70 - 79 | M | Not yet recovered | Life threatening |
| SEP2011 | CHEST PAIN PRODUCT FORMULATION CHANGE | * DABIGATRAN * ATORVASTATIN | Unknown | F | unknown outcome | Not Serious |

| REPORT DATE | REACTIONS | DRUGS | AGE Group | SEX | Patient Outcome | ICH Seriousness |
|-------------|---|--|-----------|-----|----------------------------|-----------------|
| SEP2011 | RECTAL BLEEDING | * DABIGATRAN WARFARIN COMBIVENT SIMVASTATIN QUINAPRIL | 80 plus | M | Recovered without sequelae | Not Serious |
| SEP2011 | TRANSIENT ISCHAEMIC ATTACK CONVULSIONS | * DABIGATRAN WARFARIN | 80 plus | M | Died - unrelated to drug | Died |
| SEP2011 | UPPER LIMB OEDEMA | * DABIGATRAN SIMVASTATIN FRUSEMIDE QUINAPRIL ALLOPURINOL | 60 - 69 | M | Not yet recovered | Not Serious |
| SEP2011 | DYSPEPSIA | * DABIGATRAN FRUSEMIDE METOPROLOL CILAZAPRIL THYROXINE | 80 plus | F | Recovered without sequelae | Not Serious |
| SEP2011 | GASTROESOPHAGEAL REFLUX DYSPHAGIA | * DABIGATRAN FRUSEMIDE CARVEDILOL LOSARTAN | 70 plus | M | Not yet recovered | Not Serious |
| SEP2011 | MELAENA DRUG INTERACTION | I DABIGATRAN I DIPYRIDAMOLE FELODIPINE METOPROLOL BENDROFLUAZIDE | 60 - 69 | M | Recovered without sequelae | Not Serious |

| REPORT DATE | REACTIONS | DRUGS | AGE Group | SEX | Patient Outcome | ICH Seriousness |
|-------------|---|--|-----------|-----|----------------------------|-----------------|
| SEP2011 | CHEST PAIN SUBSTERNAL BACK PAIN DYSPHAGIA | * DABIGATRAN INSULIN NEUTRAL/ISOPHANE FRUSEMIDE IRPRAZIPIUM BROMIDE CARVEDILOL | 80 plus | M | Recovered without sequelae | Not Serious |
| SEP2011 | NEUTROPENIA | * DABIGATRAN METFORMIN SIMVASTATIN PREDNISONE CILAZAPRIL/HYDROCHLOROTHIAZIDE | 80 plus | F | Recovered without sequelae | Not Serious |
| SEP2011 | RECTAL BLEEDING CREATININE CLEARANCE DECREASED | * DABIGATRAN PARACETAMOL MOCLOBEMIDE DOXEPIN LAXSOL | 70 - 79 | M | Not yet recovered | Not Serious |
| SEP2011 | DYSPNOEA CONFUSION DEPRESSION | * DABIGATRAN DILTIAZEM CANDESARTAN DIGOXIN FRUSEMIDE | 80 plus | F | Recovered without sequelae | Not Serious |
| SEP2011 | DIARRHOEA RECTAL BLEEDING | * DABIGATRAN QUINAPRIL ASCORBIC ACID GLUCOSAMINE | 60 - 69 | M | Recovered without sequelae | Not Serious |
| SEP2011 | PRURITUS SKIN DISCOLOURATION SKIN DRY | * DABIGATRAN METFORMIN FRUSEMIDE SIMVASTATIN THYROXINE | 60 - 69 | F | Not yet recovered | Not Serious |