



IRISH MEDICINES BOARD

**Suspected adverse reactions associated with Cipramil received by the Irish Medicines Board
to 8th November 2010**

Brief Information Report
(Sort by AER Number)

AER Number	AER Summary	Patient	Suspect products	Concomitant products	Reactions	Date Reported
025209	AER No : 025209 Country : IRELAND Received : 01/NOV/00 Last update:15/OCT/10	Sex : F Age :33 Y	Cipramil	Stilnoct Ponstan Forte Methadone B.P. 1%	Weight decrease	
025547	AER No : 025547 Country : IRELAND Received : 01/DEC/00 Last update:15/OCT/10	Sex : F Age :28 Y	St. John's Wort (generic) Cipramil	Vitamin B Complex Alprazolam kava Kava (generic)	Collapse transient Onset Date : 28/NOV/00	
025582	AER No : 025582 Country : IRELAND Received : 07/DEC/00 Last update:15/OCT/10	Sex : F Age :54 Y	Cipramil	Xanax	Anorgasmia	
025819	AER No : 025819 Country : IRELAND Received : 21/DEC/00 Last update:15/OCT/10	Sex : F Age :30 Y	Cipramil	Concomitant drug not available	Retinal vascular disorder NOS Onset Date : 01/AUG/00	
025903	AER No : 025903 Country : IRELAND Received : 15/JAN/01 Last update:15/OCT/10	Sex : M Age :35 Y	Cipramil	Concomitant drug not available	Anxiety Onset Date : 03/JAN/01 Tremor Onset Date : 03/JAN/01	
025943	AER No : 025943 Country : IRELAND Received : 19/JAN/01 Last update:15/OCT/10	Sex : M Age :31 Y	Cipramil	Concomitant drug not available	Hyperactivity Onset Date : 15/JAN/01	
026019	AER No : 026019 Country : IRELAND Received : 31/JAN/01 Last update:15/OCT/10	Sex : F Age :83 Y	Cipramil	Centyl K 2.5mg/573 mg Modified-release Tablets. Liquifilm Tears Ocular Lubricant Noctamid Lactulose	Itching Onset Date : 01/JAN/01	
026416	AER No : 026416 Country : IRELAND Received : 22/MAR/01 Last update:15/OCT/10	Sex : F Age :54 Y	Cipramil	Sinemet Slow Sodium AULIN	Hyponatraemia	
026417	AER No : 026417 Country : IRELAND Received : 22/MAR/01 Last update:15/OCT/10	Sex : M Age :48 Y	Cipramil Warfarin	Concomitant drug not available	Clotting time increased	
026903	AER No : 026903 Country : IRELAND Received : 08/MAY/01 Last update:15/OCT/10	Sex : F Age :19 Y	Cipramil	Concomitant drug not available	Photosensitivity reaction Onset Date : 02/MAY/01 Rash erythematous Onset Date : 02/MAY/01	

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027083	AER No : 027083 Country : IRELAND Received : 01/JUN/01 Last update:15/OCT/10	Sex : F Age :34 Y	Cipramil	Eltroxin 100 micrograms tablets	Convulsions Onset Date : 29/MAY/01	
027760	AER No : 027760 Country : IRELAND Received : 16/OCT/01 Last update:15/OCT/10	Sex : F Age :47 Y	Cipramil	Syndol Nexium Lexotan 3mg Tablets Half-Inderal LA Zopitan	Headache	
027884	AER No : 027884 Country : IRELAND Received : 02/NOV/01 Last update:15/OCT/10	Sex : M Age :25 Y	Cipramil	Concomitant drug not available	Urticaria Onset Date : 26/OCT/01 Hypotension NOS Onset Date : 26/OCT/01 Allergic reaction Onset Date : 26/OCT/01	
027913	AER No : 027913 Country : IRELAND Received : 09/NOV/01 Last update:15/OCT/10	Sex : F Age :29 Y	Cipramil	Concomitant drug not available	Convulsions Onset Date : 29/MAR/99	
027914	AER No : 027914 Country : IRELAND Received : 09/NOV/01 Last update:15/OCT/10	Sex : M Age :63 Y	Cipramil	Concomitant drug not available	Confusion aggravated Onset Date : 07/APR/01	
028640	AER No : 028640 Country : IRELAND Received : 14/MAR/02 Last update:15/OCT/10	Sex : F Age :51 Y	Cipramil	Concomitant drug not available	Tremor limb Onset Date : /Apr/01 Withdrawal syndrome Onset Date : /Apr/01	
028796	AER No : 028796 Country : IRELAND Received : 14/MAY/02 Last update:15/OCT/10	Sex : M Age :53 Y	Cipramil	Xanax	Sleep disturbed Onset Date : 07/FEB/02 Sweating increased Onset Date : 07/FEB/02 Nervousness Onset Date : 07/FEB/02 Palpitation Onset Date : 07/FEB/02	
028908	AER No : 028908 Country : IRELAND Received : 14/JUN/02	Sex : F Age :21 Y	Cipramil	Concomitant drug not available	Pruritus Onset Date : 27/MAY/02	

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	Last update:15/OCT/10					
028927	AER No : 028927 Country : IRELAND Received : 18/JUN/02 Last update:15/OCT/10	Sex : F	Cipramil	Antimet	Mouth dry Onset Date : 12/JUN/02 Head discomfort Onset Date : 12/JUN/02 Nausea Onset Date : 12/JUN/02 Tremor limb Onset Date : 12/JUN/02 Dizziness Onset Date : 12/JUN/02	
028928	AER No : 028928 Country : IRELAND Received : 18/JUN/02 Last update:15/OCT/10	Sex : F	Cipramil	Concomitant drug not available	Convulsions Onset Date : 13/JUN/02	
028951	AER No : 028951 Country : IRELAND Received : 29/MAY/02 Last update:15/OCT/10	Sex : F Age :36 Y	Cipramil	Concomitant drug not available	Asphyxiation Onset Date : /Oct/01	
029053	AER No : 029053 Country : IRELAND Received : 10/JUL/02 Last update:15/OCT/10	Sex : M Age :38 Y	Cipramil	Concomitant drug not available	Acid indigestion Indigestion Heartburn	
029061	AER No : 029061 Country : IRELAND Received : 18/JUL/02 Last update:15/OCT/10	Sex : F	Cipramil	Concomitant drug not available	Sleep disturbed Nausea Anger Agitation	
029129	AER No : 029129 Country : IRELAND Received : 12/AUG/02 Last update:15/OCT/10	Sex : F Age :24 Y	Cipramil	MICROLITE	Teeth-grinding	
029292	AER No : 029292 Country : IRELAND Received : 17/SEP/02 Last update:15/OCT/10	Sex : F Age :62 Y	Cipramil	Concomitant drug not available	Anxiety Onset Date : 15/AUG/02 Insomnia Onset Date : 15/AUG/02 Nausea Onset Date : 15/AUG/02	

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AER Number	AER Summary	Patient	Suspect products	Concomitant products	Reactions	Date Reported
029331	AER No : 029331 Country : IRELAND Received : 01/OCT/02 Last update:15/OCT/10	Sex : F Age :48 Y	Cipramil	Calcichew 500mg Chewable Tablets Dalmane MINOCIN SA AULIN	Xerostomia Onset Date : 15/AUG/02	
029332	AER No : 029332 Country : IRELAND Received : 02/OCT/02 Last update:15/OCT/10	Sex : M Age :32 Y	Cipramil	Viagra	Joint pain	
029483	AER No : 029483 Country : IRELAND Received : 31/OCT/02 Last update:15/OCT/10	Sex : M Age :59 Y	Cipramil	Molipaxin	Myoclonic jerks Onset Date : 06/APR/02	
029485	AER No : 029485 Country : IRELAND Received : 31/OCT/02 Last update:15/OCT/10	Sex : M Age :70 Y	Cipramil Epanutin	Concomitant drug not available	Memory impairment Onset Date : /Oct/02 Drug level increased Onset Date : /Oct/02 Speech disorder Onset Date : /Oct/02 Drowsiness Onset Date : /Oct/02 Somnolence Movement disorder NOS Onset Date : /Oct/02 Somnolence Onset Date : /Oct/02	
029559	AER No : 029559 Country : IRELAND Received : 01/NOV/02 Last update:15/OCT/10	Sex : M	Cipramil	Olanzapine (g)	Liver function tests abnormal NOS NOS	
029593	AER No : 029593 Country : IRELAND Received : 20/NOV/02 Last update:15/OCT/10	Sex : M	Cipramil	Concomitant drug not available	Liver function tests abnormal NOS NOS	
029616	AER No : 029616 Country : IRELAND Received : 25/NOV/02 Last update:15/OCT/10	Sex : F Age :65 Y	EFEXOR Cipramil Frumil Double Strength	Risedronate Sodium Levothyroxine (g) Ramipril (generic) Acetylsalicyclic acid Zopiclone	Hyponatraemia Onset Date : 28/APR/02 Hyponatraemia Onset Date : 28/APR/02	

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AER Number	AER Summary	Patient	Suspect products	Concomitant products	Reactions	Date Reported
029912	AER No : 029912 Country : IRELAND Received : 27/JAN/03 Last update:15/OCT/10	Sex : M Age :73 Y	Cipramil	Sinemet Plus Combivent Metered Beclazone Inhaler Lipostat Amlodipine (generic) Aspirin	Torsade de pointes Onset Date : 17/JAN/03	
030024	AER No : 030024 Country : IRELAND Received : 19/FEB/03 Last update:15/OCT/10	Sex : F	Cipramil	RIVOTRIL CARBAMAZEPINE (generic) Lamotrigine	Sudden death Onset Date : 04/SEP/01 Drug level increased Onset Date : 04/SEP/01 Choking Onset Date : 04/SEP/01	
030088	AER No : 030088 Country : IRELAND Received : 04/MAR/03 Last update:15/OCT/10	Sex : F Age :53 Y	Cipramil LEXAPRO	Neurontin Zomig 2.5 mg Tablets Zimovane Eltroxin 50 microgram Tablets.	Taste metallic Taste perversion Onset Date : 08/JAN/03	
030096	AER No : 030096 Country : IRELAND Received : 05/MAR/03 Last update:15/OCT/10	Sex : M	Cipramil	Depixol	Overdose effect	
030207	AER No : 030207 Country : IRELAND Received : 04/MAR/03 Last update:15/OCT/10	Sex : M Age :68 Y	Cipramil	Concomitant drug not available	Anorgasmia Sensory disturbance	
030208	AER No : 030208 Country : IRELAND Received : 07/MAR/03 Last update:15/OCT/10	Sex : M Age :47 Y	Cipramil	Concomitant drug not available	Anorgasmia	
030209	AER No : 030209 Country : IRELAND Received : 07/MAR/03 Last update:15/OCT/10	Sex : M Age :53 Y	Cipramil	Concomitant drug not available	Sensory disturbance Anorgasmia	
030317	AER No : 030317 Country : IRELAND Received : 01/MAY/03 Last update:15/OCT/10	Sex : F Age :40 Y	Cipramil PROTHIADEN	Concomitant drug not available	Weight decrease Muscle weakness NOS	
030318	AER No : 030318 Country : IRELAND Received : 01/MAY/03 Last update:15/OCT/10	Sex : F Age :23 Y	Cipramil	Diazepam (g)	Erythema multiforme Onset Date : 15/APR/03	

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AER Number	AER Summary	Patient	Suspect products	Concomitant products	Reactions	Date Reported
030548	AER No : 030548 Country : IRELAND Received : 20/JUN/03 Last update:15/OCT/10	Sex : M	Cipramil	Concomitant drug not available	Cleft lip Congenital anomaly NOS	
030919	AER No : 030919 Country : IRELAND Received : 28/AUG/03 Last update:15/OCT/10	Sex : F Age :74 Y	Cipramil	Lipitor	Vision decreased	
031099	AER No : 031099 Country : IRELAND Received : 13/FEB/04 Last update:15/OCT/10	Sex : F	Cipramil	Concomitant drug not available	Hypomania	
031367	AER No : 031367 Country : IRELAND Received : 22/DEC/03 Last update:15/OCT/10	Sex : F Age :41 Y	Cipramil	Innohep 18000 Losec Mups Zimovane	Nausea Onset Date : 01/DEC/03 Diarrhoea Onset Date : 01/DEC/03 Vomiting Onset Date : 01/DEC/03	
031574	AER No : 031574 Country : IRELAND Received : 09/FEB/04 Last update:15/OCT/10	Sex : F Age :51 Y	Cipramil	Concomitant drug not available	Headache Onset Date : 21/DEC/03 Face oedema Onset Date : 21/DEC/03 Flushing Onset Date : 21/DEC/03 Throat tightness Onset Date : 21/DEC/03	
031639	AER No : 031639 Country : IRELAND Received : 04/NOV/10 Last update:05/NOV/10	Sex : M Age :60 Y	Cipramil	Modecate Ensure/Enlive/Form- ance Nexium Cogentin Fybogel Lactulose Chlorpromazine Diazepam Benztropine mesylate (g) PERIACTIN MOVICOL	Drug level increased	
031812	AER No : 031812 Country : IRELAND Received : 30/MAR/04 Last update:15/OCT/10	Sex : F Age :54 Y	Cipramil Chlorpromazine BP	AKINETON Vitamin C Folic Acid Gaviscon 250 Modecate Concentrate	Overdose effect Onset Date : 26/AUG/03 Fibrillation ventricular Onset Date : 26/AUG/03	

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AER Number	AER Summary	Patient	Suspect products	Concomitant products	Reactions	Date Reported
				Dalmapam 15mg Hard Capsules.		
032220	AER No : 032220 Country : IRELAND Received : 04/NOV/10 Last update:05/NOV/10	Sex : M Age :38 Y	CLOZARIL Cipramil	Valium Paracetamol (generic) Risperidone (generic) Dalmane	Drug level increased Onset Date : 11/MAY/04 Accidental overdose Onset Date : 11/MAY/04	
032695	AER No : 032695 Country : IRELAND Received : 04/OCT/04 Last update:15/OCT/10	Sex : F	Cipramil	Concomitant drug not available	Purpura	
033110	AER No : 033110 Country : IRELAND Received : 04/NOV/10 Last update:05/NOV/10	Sex : F	Cipramil Avandia 4mg tablet	Amitriptyline (generic) Metformin (generic) GALFER	Drug level increased Onset Date : /Oct/03 Myocardial infarction Onset Date : /Oct/03	
033113	AER No : 033113 Country : IRELAND Received : 23/DEC/04 Last update:15/OCT/10	Sex : M Age :39 Y	Cipramil	Concomitant drug not available	Depression Onset Date : /Aug/04 Electric shock sensation Onset Date : /Aug/04 Sleep disturbed Onset Date : /Aug/04 Dreaming abnormal Onset Date : /Aug/04 Withdrawal syndrome Onset Date : /Aug/04	
033319	AER No : 033319 Country : IRELAND Received : 07/FEB/05 Last update:15/OCT/10	Sex : F Age :59 Y	Cipramil MicardisPlus	Xanax Lipitor 20 mg Film-coated Tablets Nu-Seals MOTILIUM Rx	Confusion Onset Date : 02/FEB/05 Hyponatraemia Onset Date : 02/FEB/05	
033652	AER No : 033652 Country : IRELAND Received : 25/APR/05 Last update:15/OCT/10	Sex : F Age :64 Y	Cipramil	Concomitant drug not available	Withdrawal syndrome Hallucination Sweating increased	
034480	AER No : 034480 Country : IRELAND Received : 23/SEP/05 Last update:15/OCT/10	Sex : F	Cipramil	NORTEM	Suicidal tendency	

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AER Number	AER Summary	Patient	Suspect products	Concomitant products	Reactions	Date Reported
034559	AER No : 034559 Country : IRELAND Received : 04/NOV/10 Last update:05/NOV/10	Sex : F Age :23 M	Cipramil	Concomitant drug not available	Renal tubular disorder Onset Date : /Sep/05 Accidental overdose Onset Date : /Sep/05 Hyponatraemia Onset Date : /Sep/05 Hypercalcaemia Onset Date : /Sep/05 Hyperkalaemia Onset Date : /Sep/05	
034849	AER No : 034849 Country : IRELAND Received : 30/NOV/05 Last update:15/OCT/10	Sex : F Age :64 Y	Cipramil	Buram Esomeprazole (g) ASPIRIN 75MGS (generic) Distalgesic AULIN DELTACORTRIL ENTERIC	Convulsions Onset Date : 14/JUN/05 Hyponatraemia Onset Date : 14/JUN/05	
034878	AER No : 034878 Country : IRELAND Received : 05/DEC/05 Last update:15/OCT/10	Sex : F Age :48 Y	Cipramil	Durogesic DTrans Isoptin 40 mg Film-coated Tablets Zimovane Diazepam	Arthralgia Onset Date : 21/OCT/05 Mobility decreased Onset Date : 21/OCT/05 Oedema legs Onset Date : 21/OCT/05 Myalgia Onset Date : 21/OCT/05	
035151	AER No : 035151 Country : IRELAND Received : 30/MAR/06 Last update:15/OCT/10	Sex : F Age :43 Y	Cipramil	SERETIDE 125 EVOHALER 25/125microgram/do- se pressur	Paraesthesia Onset Date : /Sep/05 Myalgia Onset Date : /Sep/05 Drug withdrawal syndrome Onset Date : /Sep/05	
035536	AER No : 035536 Country : IRELAND Received : 28/APR/06 Last update:15/OCT/10	Sex : F Age :65 Y	Cipramil EPILIM CHRONO	Cardicor Rythmodan Retard Tablets ZOCOR WARFARIN (generic)	Tremor	
035995	AER No : 035995 Country : IRELAND Received : 03/JUL/06 Last update:15/OCT/10	Sex : F	Cipramil	Concomitant drug not available	Hyponatraemia	

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AER Number	AER Summary	Patient	Suspect products	Concomitant products	Reactions	Date Reported
035996	AER No : 035996 Country : IRELAND Received : 04/AUG/06 Last update:15/OCT/10	Sex : F Age :92 Y	Cipramil	Trimoptin Imdur Movicol Stilnoct 5mg Film-Coated Tablets NEXIUM Eltroxin 50 micrograms Tablets.	Hyponatraemia Onset Date : 12/MAY/06	
037176	AER No : 037176 Country : IRELAND Received : 28/MAR/07 Last update:15/OCT/10	Sex : M Age :31 Y	Cipramil 40mg/ml Oral drops, solution.	Concomitant drug not available	Feeling strange Change in dose : Drug withdrawn Onset Date : 01/OCT/06 Electric shock sensation Change in dose : Drug withdrawn Onset Date : 01/OCT/06 Agitation Change in dose : Drug withdrawn Onset Date : 01/OCT/06 Depressed mood Change in dose : Drug withdrawn Onset Date : 01/OCT/06 Fatigue Change in dose : Drug withdrawn Onset Date : 01/OCT/06	
037749	AER No : 037749 Country : IRELAND Received : 26/JUN/07 Last update:15/OCT/10	Sex : F Age :65 Y	Cipramil ENTACT	Concomitant drug not available	Rash Change in dose : Drug withdrawn Onset Date : 01/APR/07 Rash aggravated Onset Date : 01/APR/07	
037779	AER No : 037779 Country : IRELAND Received : 17/APR/08 Last update:15/OCT/10	Sex : F Age :37 Y	Stemetil Cipramil	Concomitant drug not available	Dystonia Change in dose : Drug withdrawn Drug withdrawal syndrome Hyperemesis Anxiety Change in dose : Drug withdrawn Agitation Change in dose : Drug withdrawn Suicidal tendency Change in dose : Drug withdrawn	
038178	AER No : 038178 Country : IRELAND Received : 02/JAN/08	Sex : F Age :79 Y	Cipramil Levodopa	FYBOGEL CITRUS Amlodipine (generic)	Serotonin syndrome Change in dose : Drug withdrawn Onset Date : 18/SEP/07	

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AER Number	AER Summary	Patient	Suspect products	Concomitant products	Reactions	Date Reported
	Last update:15/OCT/10			Paracetamol (generic)		
038305	AER No : 038305 Country : IRELAND Received : 08/FEB/08 Last update:15/OCT/10	Sex : F Age :47 Y	Cipramil	Arimidex 1mg Film-coated Tablets Ideos TAMOXIFEN Lipitor 10 mg Film-coated Tablets Beconase 50 micrograms Aqueous Nasal Spray	Postnasal drip Spasms Onset Date : 01/FEB/07 Cough Onset Date : 01/FEB/07 Sinusitis Onset Date : 01/FEB/07	
038548	AER No : 038548 Country : IRELAND Received : 13/DEC/07 Last update:15/OCT/10	Sex : F	Cipramil	Concomitant drug not available	Purpura thrombocytopenic	
039155	AER No : 039155 Country : IRELAND Received : 22/APR/08 Last update:15/OCT/10	Sex : M Age :81 Y	Cipramil Zolpidem (g) (g)	Oxycontin Aspirin (generic)	Memory impairment Change in dose : maintaine Onset Date : 30/JAN/08 Restless legs Change in dose : maintaine Onset Date : 30/JAN/08 Slurred speech Change in dose : maintaine Onset Date : 30/JAN/08	
039564	AER No : 039564 Country : IRELAND Received : 04/NOV/10 Last update:08/NOV/10	Sex : F Age :20 Y	Cipramil	Concomitant drug not available	Suicide Onset Date : 01/APR/04	
039688	AER No : 039688 Country : IRELAND Received : 04/NOV/10 Last update:08/NOV/10	Sex : F Age :1 D	Cipramil	Concomitant drug not available	Apnoea Onset Date : 08/MAR/08	
039750	AER No : 039750 Country : IRELAND Received : 23/JUL/07 Last update:15/OCT/10	Sex : F	Cipramil	Concomitant drug not available	Migraine Change in dose : Unknown	
041429	AER No : 041429 Country : IRELAND Received : 16/JAN/09 Last update:15/OCT/10	Sex : F	Cipramil	LOSEC MUPS Aprovel CARDURA 1 mg Tablets Lipitor 10 mg Film-coated Tablets Aspirin (generic) Daktarin	Vomiting Change in dose : Drug withdrawn Hyponatraemia SER :*** Change in dose : Drug withdrawn Syncope Change in dose : Drug withdrawn	

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041617	AER No : 041617 Country : IRELAND Received : 30/JUL/09 Last update:15/OCT/10	Sex : M	Cipramil Amitriptyline Efexor 37.5 mg Tablets Gamanil Reboxetine	Xanax (g) ZIMOVANE (generic) Arcoxia Zyban	Burning sensation SER :*** Change in dose : Drug withdrawn Burning sensation	
041651	AER No : 041651 Country : IRELAND Received : 18/FEB/09 Last update:15/OCT/10	Sex : F	Cipramil	Concomitant drug not available	Hyponatraemia Change in dose : Drug withdrawn Serum ferritin increased Change in dose : Drug withdrawn Thrombocytosis SER :*** Change in dose : Drug withdrawn	
042450	AER No : 042450 Country : IRELAND Received : 10/JUN/09 Last update:15/OCT/10	Sex : F Age :31 Y	Cipramil	Concomitant drug not available	Hair loss Change in dose : Drug withdrawn	
042485	AER No : 042485 Country : IRELAND Received : 04/JUN/09 Last update:15/OCT/10	Sex : M	Cipramil	Concomitant drug not available	Completed suicide SER :*** Change in dose : Unknown	
042541	AER No : 042541 Country : IRELAND Received : 22/JUL/09 Last update:15/OCT/10	Sex : F	Cipramil	Concomitant drug not available	Raised LFTs SER :*** Change in dose : Unknown	
042907	AER No : 042907 Country : IRELAND Received : 06/APR/10 Last update:15/OCT/10	Sex : M Age :66 Y	Cipramil Cardura XL Perindopril (g)	Omesar Zanidip 10mg film coated tablets	Tremor Change in dose : Drug withdrawn Onset Date : 23/MAY/09 Defecation urgency Onset Date : 23/MAY/09 Sweating SER :*** Change in dose : Drug withdrawn Onset Date : 23/MAY/09 Defaecation frequency increased d Change in dose : Drug withdrawn Onset Date : 23/MAY/09 Eye irritation Change in dose : Drug withdrawn Onset Date : 23/MAY/09 Gastrointestinal upset Change in dose : Drug withdrawn	

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					Onset Date : 23/MAY/09 Sweating increased Onset Date : 23/MAY/09	
043226	AER No : 043226 Country : IRELAND Received : 07/MAY/10 Last update:15/OCT/10	Sex : M Age :22 Y	Cipramil CITROL	Concomitant drug not available	Intentional overdose Change in dose : Unknown Homicide Change in dose : Unknown Suicide Change in dose : Unknown Agitation Change in dose : Unknown Onset Date : 16/AUG/09 Drug maladministration Stab wound Change in dose : Unknown Tongue swelling non-specific Change in dose : Unknown Onset Date : 16/AUG/09 Overdose intentional Suicide attempt	
045600	AER No : 045600 Country : IRELAND Received : 06/OCT/10 Last update:15/OCT/10	Sex : F Age :68 Y	Cipramil Capecitabine (g)	Tinzaparin (generic) Augmentin Morphine sulphate (generic) Lansoprazole (generic) Docusate (g) Cyclizine (generic) Lentizol QUININE (g) Diazepam (g) Zolpidem tartrate (g) Septrin 80mg/400mg Tablets	Off label use Onset Date : 03/FEB/10 Anaemia Onset Date : 03/FEB/10 Anaemia SER :*** Onset Date : 03/FEB/10 Psychosis Onset Date : 03/FEB/10	
045955	AER No : 045955 Country : IRELAND Received : 09/APR/10 Last update:15/OCT/10	Sex : F Age :66 Y	Cipramil	Lamictal	Diarrhoea SER :*** Change in dose : Drug withdrawn	
20212	AER No : 20212 Country : IRELAND Received : 06/DEC/96 Last update:15/OCT/10	Sex : M Age : Y	Cipramil	Zimovane	Euphoria Onset Date : 29/OCT/96	

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20657	AER No : 20657 Country : IRELAND Received : 07/JUL/97 Last update:15/OCT/10	Sex : F Age :87 Y	Cipramil	Erythromycin Tryptizol Lustral Duphalac Vitan ASPIRIN 75MGS (generic)	Heart block Onset Date : 26/OCT/96 Rash Onset Date : 26/OCT/96 Hyponatraemia Onset Date : 26/OCT/96	
20779	AER No : 20779 Country : IRELAND Received : 18/AUG/97 Last update:15/OCT/10	Sex : F Age :28 Y	Cipramil	Concomitant drug not available	Mouth dry Onset Date : 30/JUL/97 Nausea Onset Date : 30/JUL/97 Spasms Onset Date : 30/JUL/97 Vomiting Onset Date : 30/JUL/97	
20951	AER No : 20951 Country : IRELAND Received : 15/SEP/97 Last update:15/OCT/10	Sex : F Age :34 Y	Cipramil	Concomitant drug not available	Migraine Onset Date : 27/AUG/97	
21219	AER No : 21219 Country : IRELAND Received : 01/DEC/97 Last update:15/OCT/10	Sex : F	Cipramil	ALCOHOL (generic)	Nausea Vomiting	
21383	AER No : 21383 Country : IRELAND Received : 26/JAN/98 Last update:15/OCT/10	Sex : F Age :79 Y	Cipramil	Fruco 40 mg/5 mg Tablets Lanoxin Caprin	Tremor	
21497	AER No : 21497 Country : IRELAND Received : 18/MAR/98 Last update:15/OCT/10	Sex : M Age :54 Y	Cipramil	Concomitant drug not available	Pruritus Onset Date : 16/FEB/98	
21559	AER No : 21559 Country : IRELAND Received : 07/APR/98 Last update:15/OCT/10	Sex : F Age :58 Y	Cipramil	Concomitant drug not available	Rash Dermatitis	
21579	AER No : 21579 Country : IRELAND Received : 15/APR/98 Last update:15/OCT/10	Sex : M Age :37 Y	Cipramil	Concomitant drug not available	Acne	
21580	AER No : 21580 Country : IRELAND	Sex : F Age :23 Y	Cipramil	Librium	Acne	

Brief Information Report
(Sort by AER Number)

AER Number	AER Summary	Patient	Suspect products	Concomitant products	Reactions	Date Reported
	Received : 15/APR/98 Last update:15/OCT/10					
21650	AER No : 21650 Country : IRELAND Received : 13/MAY/98 Last update:05/NOV/10	Sex : F	CIPRAMIL	Concomitant drug not available	MYALGIA	
21727	AER No : 21727 Country : IRELAND Received : 01/MAY/98 Last update:15/OCT/10	Sex : F Age :69 Y	Cipramil	Beclazone 250 Inhaler Oxivent Inhaler Surmontil	Nausea Onset Date : 24/APR/98	
22103	AER No : 22103 Country : IRELAND Received : 16/JUN/98 Last update:15/OCT/10	Sex : F Age :38 Y	Cipramil	Kliogest 2mg/	Nausea Agitation Dizziness Light-headed feeling	
22747	AER No : 22747 Country : IRELAND Received : 29/JUL/98 Last update:15/OCT/10	Sex : F Age :56 Y	Cipramil	Concomitant drug not available	Allergic reaction	
23634	AER No : 23634 Country : IRELAND Received : 29/MAR/99 Last update:15/OCT/10	Sex : F Age :83 Y	Cipramil	Rocaltrol Dopram Frumil ASPIRIN 75MGS (generic)	Depression aggravated	
23898	AER No : 23898 Country : IRELAND Received : 20/MAY/99 Last update:15/OCT/10	Sex : M Age :40 Y	Cipramil	Inderal	Hypercholesterolaemia Onset Date : 01/APR/99	
23899	AER No : 23899 Country : IRELAND Received : 04/NOV/10 Last update:08/NOV/10	Sex : F Age :36 Y	Cipramil	Concomitant drug not available	Death intrauterine Onset Date : 05/MAY/99 DRUG EXPOSURE DURING PREGNANCY	
24048	AER No : 24048 Country : IRELAND Received : 20/AUG/99 Last update:15/OCT/10	Sex : F Age :50 Y	Cipramil	Concomitant drug not available	Retching Onset Date : 12/AUG/99 Diarrhoea Onset Date : 12/AUG/99 Nausea Onset Date : 12/AUG/99	
24151	AER No : 24151	Sex : F	Cipramil	Concomitant drug	Drowsiness	

Brief Information Report
(Sort by AER Number)

AER Number	AER Summary	Patient	Suspect products	Concomitant products	Reactions	Date Reported
	Country : IRELAND Received : 05/OCT/99 Last update:15/OCT/10	Age :29 Y		not available	Onset Date : 20/AUG/99 Acne Onset Date : 20/AUG/99	
24172	AER No : 24172 Country : IRELAND Received : 26/OCT/99 Last update:15/OCT/10	Sex : F Age :39 Y	Cipramil	Concomitant drug not available	Galactorrhoea Onset Date : 01/SEP/98	
24224	AER No : 24224 Country : IRELAND Received : 04/NOV/99 Last update:15/OCT/10	Sex : F Age :67 Y	Cipramil	Concomitant drug not available	Headache Onset Date : 12/OCT/99 Insomnia Onset Date : 12/OCT/99 Palpitation Onset Date : 12/OCT/99 Nausea Onset Date : 12/OCT/99	
24248	AER No : 24248 Country : IRELAND Received : 16/NOV/99 Last update:15/OCT/10	Sex : F	Cipramil	Concomitant drug not available	Agitation	
24398	AER No : 24398 Country : IRELAND Received : 27/JAN/00 Last update:15/OCT/10	Sex : F Age :98 Y	Cipramil	Liquifilm Tears Ocular Lubricant PINAMET CIMETIDINE	Sudden death Onset Date : 23/JAN/00	
24451	AER No : 24451 Country : IRELAND Received : 23/FEB/00 Last update:15/OCT/10	Sex : M Age :54 Y	Cipramil	Tegretol Caprin	Rash maculo-papular Onset Date : 14/FEB/00	
24589	AER No : 24589 Country : IRELAND Received : 24/MAR/00 Last update:15/OCT/10	Sex : F Age :29 Y	Cipramil	Eltroxin 100 FEMODENE	Emotional lability Onset Date : 08/MAR/00 Nausea Onset Date : 08/MAR/00 Weakness generalized Onset Date : 08/MAR/00 Dizziness Onset Date : 08/MAR/00 Headache Onset Date : 08/MAR/00	
24751	AER No : 24751 Country : IRELAND	Sex : M	Cipramil	Concomitant drug not available	Sleepiness	

Brief Information Report
(Sort by AER Number)

AER Number	AER Summary	Patient	Suspect products	Concomitant products	Reactions	Date Reported
	Received : 25/MAY/00 Last update:15/OCT/10				Alcohol problem	
24755	AER No : 24755 Country : IRELAND Received : 25/MAY/00 Last update:15/OCT/10	Sex : F Age :47 Y	Cipramil Lustral	Concomitant drug not available	Breast enlargement female	
24777	AER No : 24777 Country : IRELAND Received : 04/NOV/10 Last update:05/NOV/10	Sex : F Age :78 Y	Cipramil DF 118	Aspirin Cystrin CR GLYCERYL TRINITRATE (generic) Nu-Seals 75 IBUPROFEN Bitartrate (generic)	Shock circulatory Onset Date : 23/SEP/99 Overdose effect	
24865	AER No : 24865 Country : IRELAND Received : 07/JUL/00 Last update:15/OCT/10	Sex : F Age :56 Y	Prempak-C Cipramil	Atenolol	Vaginal haemorrhage	
24967	AER No : 24967 Country : IRELAND Received : 04/NOV/10 Last update:05/NOV/10	Sex : F Age :50 Y	Cipramil	Concomitant drug not available	Visual disturbance Eye abnormality Onset Date : 20/JUL/00	

* Deleted Record
^ Not Relevant

Total number of AERs : <112>



STATEMENT TO ACCOMPANY **ADVERSE DRUG REACTION (ADR) DATA RELEASED BY THE IMB**

Introduction

This document provides background information on the IMB's adverse drug reaction (ADR) reporting system and provides advice on interpretation of information collected through this system.

Spontaneous ADR Reports

The spontaneous monitoring system was established in 1968. Reports of suspected ADRs are received from healthcare professionals and pharmaceutical companies. Anonymised report details are included on a computerised database to facilitate processing and evaluation of reports.

Information collected through this system is an important method of monitoring drug safety in normal clinical practice, by increasing knowledge about known adverse drug reactions and also by acting as an early warning system for the identification of previously unrecognised adverse reactions. Such information is one of the tools used by the IMB in its ongoing safety evaluation of marketed drugs and is vital in identifying drugs where a change in their authorisation (licence) status is required such as restriction in usage, additional warnings and precautions for use, or rarely, withdrawal from the marketplace.

The IMB issues a Drug Safety Newsletter which is circulated to doctors, dentists and pharmacists three or four times a year, providing updated information on adverse drug reactions and providing advice on safe use of specific medicines. Copies of these newsletters are available from the Pharmacovigilance Unit, Irish Medicines Board, Earlsfort Centre, Earlsfort Terrace, Dublin 2, Ireland. Phone 01-6764971, Fax 01-6767836.

ADR Listing

- Lists all the reactions reported to have occurred in association with a suspected drug substance.
- Lists all reactions included on the original report (please note that many reports contain more than one reaction, therefore the total number of reactions may exceed the number of reports received for the drug). Each report relates to one patient.
- Lists reactions for a specific drug substance irrespective of whether the reporter provided the approved drug substance name or a brand name of that substance. Brand names are included in the listing if they have been provided.
- Includes data for reports when the drug substance is given either as a single constituent or combination (multi-constituent product). In the case of the latter it may not be always possible to identify which (if any) of the drug substances in the combination product was responsible for a particular reaction.
- Uses adverse reaction terms known as "preferred terms". This system is used in order to ensure consistency of terminology and facilitate exchange of information with pharmaceutical companies and international bodies.



Guidance on Interpretation of ADR Listings

Interpretation of the data in an ADR listing should take into account the following:

- Reports submitted to the IMB in many instances arise from suspicions occurring during observation of an unexpected and/or unwanted event.
- In many cases only limited details about each suspected adverse reaction report are received.
- Numerical comparisons should not be made between reactions associated with different drugs on the basis of the data included in listings alone. Comparisons may be misleading because of the limitations of the data.
- The inclusion of a particular reaction on the listing does not necessarily mean it has been caused by the suspect drug. Many factors have to be taken into account in assessing a causal relationship including temporal association, the possible contribution of concomitant medication, and the underlying disease.
- Interpretation of reactions to medicines in cases where multiple other therapies have been used requires special care. This is particularly relevant for vaccines as many are administered in combination. In these circumstances it may be difficult to ascribe a causal reaction to an individual vaccine or drug.
- Certain reported reactions are conditions which often occur spontaneously. In these cases there may be a temporal relationship between the medicine and the reaction which is not necessarily causal. This applies particularly to vaccines.
- The number of reports received should not be used as a basis for determining the incidence of a reaction as neither the total number of reactions occurring, nor the number of patients using the drug is known. ADR reporting rates are influenced by the seriousness of the reactions, their ease of recognition and the extent of use of a particular drug. Report rates may also be stimulated by promotion and publicity about a drug.
- Reporting tends to be highest for newly authorised medicines during the first one or two years on the market and then falls off over time.

Publication

If you wish to copy either this listing or circulate this listing or information contained within it to others please ensure a copy of this note is also provided. The IMB encourages use of data from the reporting system in publications but wishes to facilitate interpretation of the data. For this reason, we request that a copy of any proposed publications should be sent to the IMB for approval. Copies of proposed manuscripts and requests to quote data should be addressed to the Medical Director, Irish Medicines Board, Earlsfort Centre, Earlsfort Terrace, Dublin 2. We shall endeavour to respond to all requests quickly.

ADR REPORTING IS VITAL FOR DRUG SAFETY, PLEASE SUPPORT THE REPORTING SCHEME BY NOTIFYING SUSPECTED ADVERSE DRUG REACTIONS.

Every effort has been made to ensure that the information contained in line listings is accurate and true. The content of line listings are believed to be correct at the time of compilation, and are a direct representation of the data currently held on our database. The Irish Medicines Board, its servants, agents and employees disclaim all liability for the accuracy, completeness, or usefulness of any information and for any error or omission therein. © Copyright of the Irish Medicines Board