

Product Licence Number	Company Name	Product Name	Active Ingredients	Indications	Date of Authorisation
11311/0099	Tillomed Laboratories Limited	Gemfibrozil Tablets 600 mg	Gemfibrozil 600.000 mg	Prescription Only Medicine For the primary prevention of coronary heart disease in men between 40-55 years of age and with hyperlipidaemias who have not responded to diet and other appropriate measures. For the treatment of patients with hyperlipidaemias of Fredrickson Type IIa (hypercholesterolaemia), Fredrickson Type IIb (mixed hyperlipidaemia), Fredrickson Type III (familial dysbetalipoproteinaemia), Fredrickson Type IV (hypertriglyceridaemia) and Type V (hypertriglyceridaemia).	31st July, 2000
11311/0107	Tillomed Laboratories Limited	Tramadol Hydrochloride Effervescent Tablets 50 mg	Tramadol Hydrochloride 50.000 mg	Prescription Only Medicine The treatment and prevention of moderate to severe pain.	7th August, 2000
11311/0172	Tillomed Laboratories Limited	Acitak 200 Cimetidine 200 mg Tablets	Cimetidine 200.000 mg	Prescription Only Medicine Duodenal or benign gastric ulceration. Reflux oesophagitis. Zollinger-Ellison syndrome. Prophylaxis of stress ulceration in seriously acutely ill patients. Prophylaxis of acid aspiration syndrome.	4th August, 2000
11311/0173	Tillomed Laboratories Limited	Cimetidine 400 mg Tablets	Cimetidine 400.000 mg	Prescription Only Medicine Same as in PL 11311/0172.	4th August, 2000
11311/0174	Tillomed Laboratories Limited	Acitak 800 Cimetidine 800 mg Tablets	Cimetidine 800.000 mg	Prescription Only Medicine Same as in PL 11311/0172.	4th August, 2000
11382/0051	Eastern Pharmaceuticals Limited	Flu Strength Hot Lemon Powder	Paracetamol 1000.000	General Sales List For the relief of cold and flu symptoms.	2nd August, 2000
11723/0286	Sanofi Winthrop Limited	Trazodone Hydrochloride 50 mg Capsules	Trazodone Hydrochloride 50.000 mg	Prescription Only Medicine Anxiety Depression Mixed anxiety and depression.	18th August, 2000
11723/0287	Sanofi Winthrop Limited	Trazodone Hydrochloride 100 mg Capsules	Trazodone Hydrochloride 100.000 mg	Prescription Only Medicine Anxiety Depression Mixed anxiety and depression.	18th August, 2000
12064/0078	Aurum Pharmaceuticals Limited	Fentanyl Injection 50 mcg/ml	Fentanyl Citrate 50.000 mcg	Prescription Only Medicine Fentanyl citrate is a synthetic opioid analgesic. This presentation is formulated for use primarily intravenously. ? In low doses Fentanyl is used to provide analgesia during short surgical procedures. ? In high doses it is used as an analgesic/respiratory depressant in patients requiring assisted ventilation. ? In combination with a neuroleptic it may be used for neuroleptanalgesia. ? Fentanyl is used in the treatment of severe pain, such as the pain in myocardial infarction.	15th August, 2000
12406/0010	Link Pharmaceuticals Limited	Zimbalol XL	Bezafibrate 400.000 mg	Prescription Only Medicine Use in hyperlipidaemia of Type IIa, IIb, III, IV and V under the Fredrickson classification.	16th May, 2000
12064/0066	Aurum Pharmaceuticals Limited	Tramadol Hydrochloride Injection 50 mg/ml	Tramadol Hydrochloride 50.000 mg	Prescription Only Medicine The management (treatment and prevention) of moderate to severe pain.	2nd August, 2000
12762/0076	Goldshield Pharmaceuticals Limited	Navidrex Tablets 0.5 mg	Cyclopenthiiazide .500 mg	Prescription Only Medicine Treatment of mild to moderate hypertension; in more severe hypertension Navidrex may be used in conjunction with other antihypertensive agents. Stable, chronic heart failure of mild to moderate degree (functional class II, III), as long as creatinine clearance is > 30 ml/min. Oedema of specific origin: fluid retention in pre-menstrual syndrome only as short-term therapy and only if the gain in weight is the main symptom and is well documented; ascites due to cirrhosis of the liver in stable patients under close control; oedema associated with renal disease.	24th July, 2000
PI 13826/0140	Caseview (PL) Limited	Bricanyl Turbohaler 500 Terbutaline Sulphate 500 mcg Turbohaler	Terbutaline Sulphate 500.000 mcg	Prescription Only Medicine Bronchial asthma.	24th July, 2000
PI 13826/0209	Caseview (PL) Limited	Bezalip Mono 400 mg Tablets Bezalip Retard 400 mg	Bezafibrate 400.000 mg	Prescription Only Medicine Hyperlipidaemia.	9th August, 2000
PI 13826/0233	Caseview (PL) Limited	Adalat 10 mg	Nifedipine 10.000 mg	Prescription only Medicine Angina pectoris; hypertension.	31st August, 2000