

Product Licence Number	Company Name	Product Name	Active Ingredients	Indications	Date of Authorisation
04536/0007	Gebro Pharma GMBH	Seractil 400 mg film-coated Tablets	Dexibuprofen 400.000 mg	Prescription Only Medicine Same as in PL 04536/0005.	31st October, 2000
04569/0377	Generics [UK] Limited	Terbutaline Sulphate Nebuliser Solution 5 m./2 ml	Terbutaline Sulphate .250 % w/v	Prescription Only Medicine For the relief of severe bronchospasm in bronchial asthma and in chronic bronchitis, emphysema and other bronchopulmonary disorders in which bronchospasm is a complicating factor.	12th January, 2001
04569/0474	Generics [UK] Limited	Omeprazole Capsules 20 mg	Omeprazole Micronised 20.000 mg	Prescription Only Medicine Zollinger-Ellison syndrome Duodenal ulcer and gastric ulcer. Treatment of gastroscopically verified Helicobacter pylori-associated ulcer in combination with antibiotics. Reflux oesophagitis. As maintenance therapy to prevent recurrence in severe forms of reflux oesophagitis in patients who are subject to frequent recurrences and complications and are not controlled by intermittent therapy.	8th January, 2001
06934/0039	Ethypharm SA	Novex EC 20 mg Capsules	Omeprazole 20.000 mg	Prescription Only Medicine Treatment of oesophageal reflux disease. Treatment of duodenal and benign gastric ulcers including those complicating NSAID therapy. Relief of reflux-like symptoms (e.g. heartburn) and/or ulcer-like symptoms (e.g. epigastric pain) associated with acid-related dyspepsia. Treatment and prophylaxis of NSAID-associated benign gastric ulcers, duodenal ulcers, and gastroduodenal erosions in patients with a previous history of gastroduodenal lesions who require continued NSAID treatment. Relief of associated dyspeptic symptoms. Helicobacter pylori eradication: Relief of associated dyspeptic symptoms. Prophylaxis of acid aspiration. Zollinger-Ellison syndrome.	6th October, 2000
06934/0041	Ethypharm SA	Novex EC 10 mg Capsules	Omeprazole 10.000 mg	Prescription Only Medicine Same as in PL 06934/0039.	6th October, 2000
08137/0056	Neolab Limited	Neorhitic 75 mg Retard	Diclofenac Sodium 75.000 mg	Prescription Only Medicine Rheumatoid arthritis; osteoarthritis; acute gout; low back pain, relief of pain in fractures; acute musculo-skeletal disorders and trauma including peri-arthritis (particularly frozen shoulder), bursitis, tendinitis, tenosynovitis, dislocations, sprains and strains; ankylosing spondylitis; and the control of pain and inflammation in orthopaedic, dental and other minor surgery.	19th October, 2000
08137/0057	Neolab Limited	Neorhitic 100 mg Retard	Diclofenac Sodium 100.000 mg	Prescription Only Medicine Same as in PL 08137/0056.	19th October, 2000
08137/0064	Neolab Limited	Asmabec Spacehaler 50 mcg	Beclomethasone Dipropionate 50.000 mcg	Prescription Only Medicine (i) treatment of patients whose asthma is becoming worse, and the relief provided by bronchodilators is less effective. (ii) Treatment of patients with severe asthma who are dependent on systemic corticosteroids or adrenocorticotrophic hormone (ACTH) or its synthetic equivalent. (iii) Treatment of patients who are inadequately controlled by sodium cromoglycate in addition to bronchodilators.	2nd January, 2001
08137/0065	Neolab Limited	Asmabec Spacehaler 100 mcg	Beclomethasone Dipropionate 100.000 mcg	Prescription Only Medicine Same as in PL 08137/0064.	2nd January, 2001
08137/0066	Neolab Limited	Asmabec Spacehaler 250 mcg	Beclomethasone Dipropionate 250.000 mcg	Prescription Only Medicine (i) For those asthmatic patients who have been shown to require high doses (greater than 800-1000 micrograms daily) of Beclomethasone Dipropionate BP to control their symptoms. (ii) For those patients whose asthma is no longer controlled by maximum maintenance doses of bronchodilators and Asmabec Spacehaler 50 micrograms or Asmabec spacehaler 100 micrograms.	2nd January, 2001
11204/0061	Stada Arzneimittel AG	Doxatens 1mg Tablets	Doxazosin Mesylate 1.213 mg	Prescription Only Medicine For the treatment of essential hypertension.	2nd October, 2000