

Product Licence Number	Company Name	Product Name	Active Ingredients	Indications	Date of Authorisation
17211/0252	Polyfarma Limited	Efexor 37.5 mg Tablets	Venlafaxine Hydrochloride 42.420 mg	Prescription Only Medicine The treatment of depressive illness.	2nd July, 1999
17211/0253	Polyfarma Limited	Efexor 75 mg Tablets	Venlafaxine Hydrochloride 84.840 mg	Prescription Only Medicine Same as in PLPI 17211/0252	2nd July, 1999
17225/0002	Schein Pharmaceutical UK Limited	Benzhexol Tablets 5 mg Artane 5 mg	Benzhexol Hydrochloride 5.000 mg	Prescription Only Medicine Indicated in all forms of Parkinsonism (postencephalitic, arteriosclerotic and idiopathic). It is often useful as adjuvant therapy when treating these forms of Parkinsonism with levodopa. BENZHEXOL is effective in reducing the rigidity of muscle spasm, tremor and excessive salivation associated with Parkinsonism. BENZHEXOL is also indicated to control extrapyramidal disorders (e.g. akathisia manifested by extreme restlessness and dyskinesia characterised by spastic contractions and involuntary movements) due to central nervous system drugs such as reserpine and the phenothiazines.	1st July, 1999
17225/0005	Schein Pharmaceutical UK Limited	Ethambutol Tablets 400 mg Myambutol Tablets 400 mg	Ethambutol Hydrochloride 400.000 mg	Prescription Only Medicine The primary treatment and re-treatment of tuberculosis and for prophylaxis in cases of inactive tuberculosis or large-tuberculin-positive reaction. Myambutol should only be used in conjunction with other anti-tuberculous drugs to which the patients organisms are susceptible.	1st July, 1999
17225/0004	Fimton Limited	Ethambutol Tablets 100 mg Myambutol Tablets 100 mg	Ethambutol Hydrochloride 100.000 mg	Prescription Only Medicine The primary treatment and re-treatment of tuberculosis and for prophylaxis in cases of inactive tuberculosis or large-tuberculin-positive reaction. Myambutol should only be used in conjunction with other anti-tuberculous drugs to which the patients organisms are susceptible.	1st July, 1999
17225/0007	Schein Pharmaceutical UK Limited	Promazine Suspension Sparine Suspension	Promazine Hydrochloride 50.000 mg	Prescription Only Medicine 1. As an adjunct to the short term management of moderate to severe psychomotor agitation. 2. Agitation and restlessness in the elderly.	1st July, 1999
17246/0012	DR Regenold GMBH	Action Cold Sore Cream	Aciclovir 50.000 mg	Prescription Only Medicine Zuvogen Cream is indicated for: – treatment of herpes labialis (cold sore) in non-immunocompromised patients. – treatment of initial herpes genitalia.	24th June, 1999
17246/0013	DR Regenold GMBH	Zuvogen Cream Aciclovir Cream BP 5% w/w	Aciclovir 50.000 mg	Prescription Only Medicine Zuvogen Cream is indicated for: – treatment of herpes labialis (cold sore) in non-immunocompromised patients. – treatment of initial herpes genitalia.	24th June, 1999
00242/0345	Janssen-Cilag Limited	0.9% Sodium Chloride Injection	No atives present	Prescription Only Medicine Diluent and carrier solution for injectable drugs, intended to be used exclusively in combination with Sporanox* IV.	22nd July, 1999
03787/0621	Swingward Limited T/A Medihealth	Neoral 50 mg Capsules	Cyclosporin 50.000 mg	Prescription Only Medicine Prevention of graft rejection following organ and bone marrow transplantation. The treatment of severe psoriasis and atopic dermatitis. The treatment of severe active rheumatoid arthritis. The treatment of steroid resistant or steroid dependent nephrotic syndrome.	22nd July, 1999
03787/0677	Swingward Limited T/A Medihealth	Restandal 40 mg Capsules	Testosterone Undecanoate 40.000 mg	Prescription Only Medicine Testosterone replacement therapy in male hypogonadol disorders. Osteoporosis due to androgenic deficiency.	21st July, 1999
03787/0688	Swingward Limited T/A Medihealth	Estraderm MX 100	Oestradiol 100.000 mcg	Prescription Only Medicine Estrogen replacement therapy.	23rd July, 1999
04423/0327	Doncaster Pharmaceuticals Group Limited	Modopar 250 mg Capsules	Benserazide 50.000 mg Levodopa 200.000 mg	Prescription Only Medicine Parkinsonism.	26th July, 1999
05513/0520	Eurochem Limited	Buspar 5 mg Tablets	Buspirone Hydrochloride 5.000 mg	Prescription Only Medicine Anxiety disorders.	26th July, 1999
05513/0538	Eurochem Limited	Lamotrigine 25 mg Tablets Lamictal 25 mg Tablets	Lamotrigine 25.000 mg	Prescription Only Medicine Epilepsy.	23rd July, 1999