

| Product Licence Number | Company Name      | Product Name                                   | Active Ingredients  | Indications  | Date of Authorisation |
|------------------------|-------------------|--|---|--|-----------------------|
| 6464/0273              | Waymade PLC       | Zocor 10 mg Tablets                            | Simvastatin 10.0 mg   | For use in patients with primary hypercholesterolaemia with a Cholesterol level of 6.5 MMOL/L or greater and resistant to dietary control.<br>Prescription Only Medicine   | 16th August 1995      |
| 6464/0289              | Waymade PLC       | Zopiclone 7.5 mg Tablets                       | Zopiclone 7.5 mg  | For the short-term treatment of insomnia, including difficulties in falling asleep, nocturnal awakening and early awakening, transient, situational or chronic insomnia, and insomnia secondary to psychiatric disturbances, in situations where the insomnia is debilitating or is causing severe distress for patients.<br>Prescription Only Medicine                                | 7th August 1995       |
| 6464/0318              | Waymade PLC       | Fucidine Cream 2%                              | Fusidic Acid 2% w/w   | The treatment of primary and secondary skin infections caused by sensitive strains of staphylococcus aureus, streptococcus SPP and corynebacterium minutissimum.<br>Prescription Only Medicine   | 4th August 1995       |
| 6464/0319              | Waymade PLC       | Fucidine Ointment 2%                           | Sodium Fusidate 2% w/w  | The treatment of primary and secondary skin infections caused by sensitive strains of staphylococcus aureus, streptococcus SPP and corynebacterium minutissimum.<br>Prescription Only Medicine   | 4th August 1995       |
| 6464/0321              | Waymade PLC       | Sinemet Plus Tablets                           | Carbidopa monohydrate 25.0 mg, Levodopa 100.00 mg   | Parkinson's disease and syndrome.<br>Prescription Only Medicine.   | 8th August 1995       |
| 6464/0327              | Waymade PLC       | Motival Tablets                                | Fluphenazine Hydrochloride 500 mg, Nortriptyline Hydrochloride 11.400 mg                          | The treatment of mild to moderate mixed anxiety depressive states.<br>Prescription Only Medicine   | 1st August 1995       |
| 6464/0345              | Waymade PLC       | Duphaston Tablets/Dydrogesterone 10 mg Tablets | Dydrogesterone 10.0 mg  | For the treatment of dysmenorrhoea, endometriosis, threatened and habitual abortion (associated with proven deficiency), infertility, irregular cycles, dysfunctional bleeding (with added oestrogen), premenstrual syndrome, conditions of progesterone deficiency and to counteract the effects of unopposed oestrogen in hormone replacement therapy.<br>Prescription Only Medicine | 8th August 1995       |
| 6679/0105              | Polyfarma Limited | Lomofil 2.5 mg Tablets                         | Co-phenotrope 2.525 mg, Containing Diphenoxylate Hydrochloride 2.5 mg, Atropine Sulphate 0.025 mg | Adjunctive therapy to appropriate rehydration in diarrhoea. Control of stool formation after colostomy or ileostomy. Relief of symptoms in chronic mild ulceration colitis.<br>Prescription Only Medicine  | 8th August 1995       |
| 6679/0125              | Polyfarma Limited | Otosporin Ear Drops                            | Polymyxin B Sulphate 10.000 KU, Neomycin 3.400 KU Hydrocortisone 1.000% WV                        | The treatment of bacterial infection and inflammation of the external auditory meatus.<br>Prescription Only Medicine   | 25th July 1995        |
| 6679/0133              | Polyfarma Limited | Fucidine 2% Cream                              | Fusidic acid 2% w/w   | The treatment of primary and secondary skin infections caused by sensitive strains of staphylococcus aureus, streptococcus SPP and corynebacterium minutissimum.<br>Prescription Only Medicine   | 7th August 1995       |
| 6679/0136              | Polyfarma Limited | Otosporin Ear Drops                            | Polymyxin B Sulphate 10.000 KU Neomycin Sulphate 3.400 KU Hydrocortisone 1.000% WV                | The treatment of bacterial infection and inflammation of the external auditory meatus.<br>Prescription Only Medicine   | 20th July 1995        |
| 6679/0137              | Polyfarma Limited | Dalacin Topical Solution                       | Clindamycin Phosphate 1.000% w/v  | The treatment of acne vulgaris.<br>Prescription Only Medicine  | 1st August 1995       |
| 6679/0151              | Polyfarma Limited | Surgam 300 mg Tablets                          | Tiaprofenic Acid 300.0 mg   | Rheumatoid Arthritis, Osteoarthritis, Ankylosing Spondylitis; Low Back Pain, Musculo-Skeletal Disorders such as Fibrositis, Capsulitis, Epicondylitis and other soft tissue inflammatory conditions; Sprains and Strains, Post-Operative Inflammation and Pain, and other soft tissue injuries.<br>Prescription Only Medicine  | 14th August 1995      |
| 6679/0153              | Polyfarma Limited | Zocor 10 mg Tablets                            | Simvastatin 10.000 mg   | For use in patients with primary hypercholesterolaemia with a cholesterol level of 6.5MMOL/L or greater and resistant to dietary control.<br>Prescription Only Medicine  | 28th July 1995        |
| 6679/0155              | Polyfarma Limited | Enalapril Maleate Tablets                      | Enalapril Maleate 5.0 mg  | Hypertension: All grades of essential hypertension and renovascular hypertension.<br>Congestive heart failure: As an adjunctive therapy with digitalis and/or non-potassium sparing diuretics.<br>Prescription Only Medicine   | 8th August 1995       |
| 6679/0156              | Polyfarma Limited | Lisinopril 5 mg Tablets                        | Lisinopril Dihydrate 5.45 mg equivalent to Lisinopril Anhydrous 5.0 mg                            | Treatment of all grades of essential hypertension and renovascular hypertension. It is also indicated in the treatment of congestive heart failure as adjunctive therapy with non potassium sparing diuretics and where appropriate digitalis.<br>Prescription Only Medicine   | 15th August 1995      |
| 6679/0158              | Polyfarma Limited | Inderal LA 80 mg Capsules                      | Propranolol Hydrochloride 80.000 mg   | The management of angina,<br>Prescription Only Medicine  | 28th July 1995        |