

| <i>Product Licence Number</i> | <i>Company Name</i>                               | <i>Product Name</i>                                  | <i>Active Ingredients</i>   | <i>Indications</i>  | <i>Date of Authorisation</i> |
|-------------------------------|---|--|---|---|------------------------------|
| 08685/0014                    | Dispersa (UK) Limited t/a Ciba Vision Ophthalmics | Miochol  | Acetylcholine Chloride HSE 20-00 mg   | To obtain rapid and complete miosis after delivery of the lens in cataract surgery as well as in penetrating keratoplasty, iridectomy and other anterior segment surgery where rapid complete miosis is required.<br>Prescription Only Medicine   | 24th May 1995                |
| 08685/0015                    | Dispersa (UK) Limited t/a Ciba Vision Ophthalmics | CIBA Vision Hay Fever Eye Drops                      | Xylometazoline Hydrochloride HSE 0.050 w/v;<br>Aristazoline Sulphate HSE 0.50 w/v   | For the temporary relief of redness and itching of the eye due to seasonal and perennial allergies such as hay fever or house dust allergy.<br>Pharmacy Medicine  | 4th May 1995                 |
| 8747/0119                     | Chemilines Limited                                | Duphaston 10 mg 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              |
| 8747/0121                     | Chemilines Limited                                | Proscar Tablets/Finasteride 5 mg Tablets             | Finasteride 5.000 mg  | The treatment of benign prostatic hyperplasia (BPH) to cause regression of the enlarged prostate; improve urinary flow and improve the symptoms associated with BPH.<br>Prescription Only Medicine  | 28th July 1995               |
| 8747/0132                     | Chemilines Limited                                | Atrovent Inhaler                                     | Ipratropium Bromide 29.800 mg   | The treatment of chronic reversible airways obstruction, particularly chronic bronchitis.<br>Prescription Only Medicine   | 28th July 1995               |
| 8747/0134                     | Chemilines Limited                                | Dalacin Topical Solution                             | Clindamycin 1.0% wv   | The treatment of Acne vulgaris.<br>Prescription Only Medicine   | 4th August 1995              |
| 10256/0197                    | Stephar (UK) Limited                              | Sinemet Plus   | Cardidopa 27.0 mg<br>Levodopa 100.0 mg  | Anti-Parkinsonian agent for treatment of Parkinson's disease and syndrome.<br>Prescription Only Medicine  | 28th July 1995               |
| 10256/0210                    | Stephar (UK) Limited                              | Ponstan Forte 500 mg Tablets                         | Mefenamic Acid 500 mg   | 1. As an anti-inflammatory analgesic for the symptomatic relief of rheumatoid arthritis (including Still's disease), osteoarthritis, and pain including muscular traumatic and dental pain, headaches of most aetiology, post operative and post-partum pain.<br>2. Primary dysmenorrhoea.<br>3. Menorrhagia due to dysfunctional causes and presence of an IUD when other pelvic pathology has been ruled out.<br>Prescription Only Medicine | 20th July 1995               |
| 1032/0001                     | Resolution Chemicals Ltd.                         | Lactulose Solution Ph. Eur.                          | Lactulose Solution 100.000 wv   | For treatment of constipation and hepatic encephalopathy (hepatic coma).<br>Pharmacy Medicine   | 12th July 1995               |
| 10380/0093                    | Swinghope Limited                                 | Lioresal 10 mg                                       | Balcofen 10.000 mg  | The relief of spasticity of voluntary muscle resulting from such disorders as multiple sclerosis, other spinal lesions, e.g. tumours of the spinal cord, syringomyelia, motor neurone disease, transverse myelitis, traumatic partial section of the cord, cerebrovascular accidents, cerebral palsy, meningitis, traumatic head injury.<br>Prescription Only Medicine  | 21st July 1995               |
| 10380/0096                    | Swinghope Limited                                 | Dyazide Tablets                                      | Hydrochlorothiazide 25.00 mg<br>Triamterene 50.000 mg   | For the treatment of mild to moderate hypertension, alone or in combination with other antihypertensive drugs. It is also indicated in the control of oedema in cardiac failure, cirrhosis of the liver or nephrotic syndrome, and in that associated with corticosteroid treatment.<br>Prescription Only Medicine  | 19th July 1995               |
| 10380/0110                    | Swinghope Limited                                 | Fucidine Cream 2%                                    | Fusidic acid 2% w/w   | For 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              |
| 10380/0111                    | Swinghope Limited                                 | Fucidine Ointment 2%                                 | Sodium Fusidate 20.0 mg   | 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              |
| 10380/0112                    | Swinghope Limited                                 | Cicatrin Cream 15g                                   | Neomycin sulphate 3.3 ku<br>Zinc Bacitracin 250.0 UB<br>Aminoacetic acid 1.0% w/w<br>L-cysteine 0.2% w/w<br>Threonine.DL 0.1% w/w | Superficial bacterial infection of skin, such as in impetigo, varicose ulcers, pressure sores, trophic ulcers and burns.<br>Prescription Only Medicine  | 4th August 1995              |