

| <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> |
|-------------------------------|---------------------------------|--|---|---|------------------------------|
| 12998/0009 | Pharmaceutical Identity Limited | Canesten Cream 1% | Clotrimazole 1.0 w/w | Canesten is a broad-spectrum anti-fungal. It also exhibits activity against trichomonas, staphylococci, streptococci and bacteroides. It has no effect on lactobacilli. For the treatment of: 1. All dermatomycoses due to moulds and other fungi (e.g. Trichophyton species). 2. All dermatomycoses due to yeasts (candida species). 3. Skin diseases showing secondary infection with these fungi. 4. Candidal nappy rash, vulvitis and balanitis. POM | 24th August 1994 |
| 12998/0010 | Pharmaceutical Identity Limited | Betagan Eye Drops | Levobunolol Hydrochloride 0.5 w/v equivalent to Levobunolol 0.445 w/v | Reduction of intra-ocular pressure in chronic open-angle glaucoma and ocular hypertension. POM | 13th September 1994 |
| 12998/0015 | Pharmaceutical Identity Limited | Cefaclor 500 mg Capsules | Cefaclor 500 mg | For the treatment of the following infections due to susceptible micro-organisms: Respiratory tract infections, including pneumonia, bronchitis, exacerbations of chronic bronchitis, pharyngitis and tonsillitis, and as part of the management of sinusitis. Otitis media, skin and soft tissue infections, urinary tract infections, including pyelonephritis and cystitis. Effective in both acute and chronic urinary tract infections. Cefaclor is active against the following organisms in vitro: Alpha- and beta-haemolytic streptococci, staphylococci, including coagulase-positive, coagulase-negative and penicillinase-producing strains. Streptococcus pyogenes (group A beta-haemolytic streptococci). Branhamella catarrhalis. Escherichia coli. Proteus mirabilis. Klebsiella species. Haemophilus influenzae, including ampicillin-resistant strains. Cefaclor has no activity against Pseudomonas species or Acinetobacter species. Methicillin-resistant staphylococci and most strains of enterococci (e.g. Str. faecalis) are resistant to Cefaclor. Cefaclor is not active against most strains of Enterobacter spp Serratia spp, Morganella morganii, Proteus vulgaris and Providencia rettgeri. Cefaclor is generally effective in the eradication of streptococci from the nasopharynx, however, data establishing efficacy in the subsequent prevention of either rheumatic fever or bacterial endocarditis are not available. POM | 24th August 1994 |
| 13323/0113 | Thomas Kerfoot & Co. Limited | Naproxen Tablets BP 250 mg | Naproxen BP 250 mg | Naproxen is a non-steroidal anti-inflammatory agent indicated for the treatment of rheumatoid arthritis, osteoarthritis (degenerative arthritis), ankylosing spondylitis, acute gout, acute musculoskeletal disorders such as cervical spondylitis, lumbosacral pain, direct trauma, strains and sprains, fibrositis and tenosynovitis. POM | 19th September 1994 |
| 13323/0198 | Thomas Kerfoot & Co. Limited | Atenolol Tablets BP 50 mg | Atenolol HSE 50.00 mg | In the management of hypertension, angina pectoris, cardiac dysrhythmias and early intervention in the acute phase of myocardial infarction. POM | 19th September 1994 |
| 13323/0199 | Thomas Kerfoot & Co. Limited | Atenolol Tablets BP 100 mg | Atenolol HSE 100.00 mg | See PL13323/0198. | 19th September 1994 |
| 13424/0001 | Fujisawa Limited | Prograf Capsules 1 mg | Tacrolimus HSE 1.0 mg | Primary immunosuppression in liver and kidney allograft recipients and liver and kidney allograft rejection resistant to conventional immunosuppressive regimens. POM | 7th June 1994 |
| 13424/0002 | Fujisawa Limited | Prograf Capsules 5 mg | Tacrolimus HSE 5.0 mg | See PL13424/0001. | 7th June 1994 |
| 13424/0003 | Fujisawa Limited | Prograf Concentrate for Infusion 5 mg/ml | Tacrolimus HSE 0.59% w/v | See PI/13424/0001. | 7th June 1994 |