

Product Licence Number	Company Name	Product Name	Active Ingredients	Indications	Date of Authorisation
			contained in Enteric coated pellets 25.0 mg Sustained Release Pellets 50.0 mg	Osteoarthritis; low back pain; acute musculo-skeletal disorders and trauma such as periarthritis [especially frozen shoulder], tendinitis, tenosynovitis, bursitis, sprains, strains, and dislocations; relief of pain in fractures; ankylosing spondylitis; acute gout; control of pain and inflammation in orthopaedic, dental and other minor surgery. POM	
8381/0001	Sigma-Tau Industrie Farmaceutiche Riunite SPA	Elcarn Chewable Tablet 1 g	L-Carnitine inner salt HSE 1.0 gm	For the treatment of primary and secondary carnitine deficiency in adults and children over 12 years of age. POM	25th August 1994
8381/0003	Sigma-Tau Industrie Farmaceutiche Riunite SPA	Elcarn Injection 1 g	L-Carnitine inner salt HSE 1.0 gm	For the treatment of primary and secondary carnitine deficiency in adults, children infants and neonates. POM	25th August 1994
8747/0096	Chemilines Limited	Nizoral Shampoo	Ketoconazole 2.0 ww	Prevention and treatment of infections in which the yeast pityrosporum is likely to be involved, such as dandruff, seborrhoeic dermatitis and pityriasis and versicolor. POM	8th November 1994
08874/0002	Johnson & Johnson Limited	K-Y* (Econazole Nitrate) Spray Powder	Econazole Nitrate EP 1.0% ww	For the treatment of fungal infection of the skin. PM	8th November 1994
10592/0039	SmithKline Beecham Plc (V/a SmithKline Beecham Pharmaceuticals and/or SmithKline Beecham Vaccines)	Poliomyelitis Vaccine, Live (Oral), Ph. Eur (Monodose)	Bulk suspension containing polio virus type 1, not less than 6.0 Log <sub>10</sub> TCID <sub>50</sub> per dose Bulk suspension containing polio virus type 2, not less than 5.0 Log <sub>10</sub> TCID <sub>50</sub> per dose Bulk suspension containing polio virus type 3, not less than 5.5 Log <sub>10</sub> TCID <sub>50</sub> per dose	Active immunisation against Poliomyelitis. POM	25th August 1994
10592/0041	SmithKline Beecham Plc (V/a Beecham Research; Bencard; Bridge Pharmaceuticals; SmithKline & French Laboratories; SmithKline Beecham Pharmaceuticals)	Kytril Infusion	Granisetron Hydrochloride HSE 3.18 mg Equivalent to Granisetron 3.0 mg	Prevention or treatment of nausea and vomiting induced by cytostatic therapy. POM	31st August 1994
10592/0051	SmithKline Beecham Plc (V/a Beecham Research; Bencard; Bridge; SmithKline & French Laboratories; SmithKline Beecham Pharmaceuticals)	Co-Amoxiclav Dispersible Tablets 375 mg	Amoxicillin Trihydrate equivalent to Amoxicillin EP 250 mg Potassium Clavulanate equivalent to Clavulanic Acid HSE 125 mg	For the short term treatment of bacterial infections at the following sites: Upper respiratory tract infections (including ENT) eg. Tonsillitis, Sinusitis, Otitis Media. Lower respiratory tract infections eg. Acute and Chronic Bronchitis, Lobar and Bronchopneumonia. Genito-urinary tract infections eg. Cystitis, Urethritis, Pyelonephritis Skin and soft tissue infections. Bone and joint infections eg. Osteomyelitis. Dental infections eg. Dentoal veolar Abscess. Other infections eg. Septic Abortion, Puerperal Sepsis, Intra- Abdominal Sepsis. POM	1st November 1994
10592/0052	SmithKline Beecham Plc (V/a SmithKline Beecham Pharmaceuticals and/or SmithKline Beecham Vaccines)	Fluarix	Purified antigen fractions of inactivated Influenza viruses (cultivated in embryonated hen's eggs) corresponding to WHO selected strains (1994): A/Shandong/9/93 X-121 (H <sub>3</sub> N <sub>2</sub> ) HSE 15.0 µg* A/Singapore/6/86-like strain (H <sub>1</sub> N <sub>1</sub> ) HSE 15.0 µg* B/Panama/45/90 HSE 15.0 µg* *Expressed as µg of haemagglutinin per 0.5 ml dose	Prophylaxis against influenza in adults and children over six months of age. It is recommended in those groups regarded as being at special risk, especially the elderly (over 60 years of age) and/or subjects with the following: Diseases of the cardiovascular system, metabolic diseases (diabetes), cystic fibrosis, chronic respiratory diseases and chronic renal insufficiency, congenital or acquired immune deficiency. POM	19th August 1994
10622/0003	Cusi (UK) Limited	Cusilube	White soft paraffin BP 60.0% ww Liquid paraffin EP 30.0% ww Wool fat EP 10.0% ww	As adjunctive therapy to lubricate and protect the eye in conditions such as exposure keratitis, decreased corneal sensitivity, recurrent corneal erosions, keratitis sicca, ophthalmic surgery and non-ophthalmic surgery. PM	16th August 1994
10949/0089	Glaxo Pharmaceuticals UK Limited	Volmax Tablets 4 mg	Salbutamol Sulphate BP 4.82 mg	For the treatment of reversible airways obstruction due to asthma, because of their controlled release formulation they may be helpful in the management of nocturnal asthma. POM	1st August 1994
10949/0090	Glaxo Pharmaceuticals UK Limited	Volmax Tablets 8 mg	Salbutamol Sulphate BP 9.64 mg	See PL/10949/0089.	1st August 1994
10949/0231	Glaxo Pharmaceuticals UK Limited	Imigran Tablets 100 mg	Sumatriptan Succinate HSE 140.00 mg (equivalent to 100 mg Sumatriptan base)	For the acute relief of migraine attacks with or without aura. POM	1st August 1994
11157/0002	Novex Pharma Limited	Danlax Suspension (Co- Danthramer Suspension)	Danthron BP 25.0 mg Poloxamer 188 NF 200.0 mg	Constipation in the elderly, analgesic induced constipation in	11th August 1994