

DEPARTMENT OF HEALTH

MEDICINES CONTROL AGENCY

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Product Licences Granted

Product Licence Number	Company Name	Product Name	Active Ingredients	Indications	Date of Authorisation
0003/0337	The Wellcome Foundation Limited	Wellvone Tablets 250 mg	Atovaquone HSE 250.0 mg	Prescription Only Medicine Acute treatment of mild to moderate <i>Pneumocystis Carinii</i> pneumonia (PCP) (Alveolar-Arterial oxygen tension differences ((A-A)DO ₂) ≤ 45 MMHG (6 KPA) and oxygen tension in arterial blood (PAO ₂) ≥ 60 MMHG (8 KPA) breathing room air) in patients who are intolerant of Co-Trimoxazole therapy.	23rd August, 1994
0006/0297	Lilly Industries Limited T/A Eli Lilly and Company Limited, Dista Products Limited and Greenfield Pharmaceuticals	Humatro-II Pen 18 iu Injection	Biosynthetic Human growth Hormone HSE 18.00 iu (Somatropin RBE)	Prescription Only Medicine The long-term treatment of children who have growth failure due to an inadequate secretion of normal endogenous growth hormone and the treatment of short stature in children with Turner's syndrome, confirmed by chromosome analysis.	18th August, 1994
0006/0298	Lilly Industries Limited T/A Eli Lilly and Company Limited, Dista Products Limited and Greenfield Pharmaceuticals	Humatro-II Pen 36 iu Injection	Biosynthetic Human Growth Hormone HSE 36.00 iu (Somatropin RBE)	Prescription Only Medicine (Same as in PL 0006/0297)	18th August, 1994
0006/0299	Lilly Industries Limited T/A Eli Lilly and Company Limited, Dista Products Limited and Greenfield Pharmaceuticals	Humatro-II Pen 72 iu Injection	Biosynthetic Human Growth Hormone HSE 72.00 iu (Somatropin RBE)	Prescription Only Medicine (Same as in PL 0006/0297)	18th August, 1994
00032/0191	Upjohn Limited	Solu-Medrone 1 Gram	Methylprednisolone Sodium Succinate HSE 1.326 GM Equivalent to Methylprednisolone 1.0 GM	Prescription Only Medicine For any condition in which rapid and intense corticosteroid effect is required such as: Acute exacerbations of multiple sclerosis superimposed on a relapsing-remitting background.	5th August, 1994
00034/0326	E.R. Squibb & Sons Limited	Staril Tablets 10 mg	Fosinopril Sodium HSE 10.0 MG	Prescription Only Medicine The treatment of hypertension. Staril may be used alone as initial therapy or in combination with other antihypertensive agents. The antihypertensive effects of Staril and diuretics used concomitantly are approximately additive.	25th August, 1994
0039/0462	Evans Medical Limited	Inactivated Influenza Vaccine (Surface Antigen) PH. EUR UK Market: Fluvirin Overseas Markets: Fluvirin, Fluvirine, Evagrip. Griepvaccin and Vaccine Mot Influenza	Haemagglutinin proteins of the following strains of influenza virus: A/Singapore/6/86 (H1N1)-LIKE NLT HSE 15.00 ug A/Shangdong/9/93 (H3N2)-LIKE NLT HSE 15.00 mg B/Panama/45/90-LIKE NLT HSE 15.00 mg Neuraminidase proteins are also present	Prescription Only Medicine For protection against Influenza.	25th August, 1994
0076/0171	Cilag Limited T/A Ortho Division of Cilag Limited	Renova*	Tretinoin EP 0.05% w/w	Prescription Only Medicine For the topical treatment of mottled hyperpigmentation, roughness and fine wrinkling of photodamaged skin due to chronic sun exposure.	16th August, 1994
00076/0175	Cilag Limited T/A Cilag Biotech	Eporex Injection 2000 IU/ML	Epoetin alfa (Recombinant Human Erythropoietin HSE 2000 IU	Prescription Only Medicine The treatment of anaemia in adult cancer patients receiving platinum containing chemotherapy regimens.	19th August, 1994
00076/0183	Cilag Limited T/A Cilag Biotech	Eporex Injection 2000 IU/ML	Epoetin alfa (Recombinant Human Erythropoietin HSE 2000 IU	Prescription Only Medicine Eporex can be used to increase the yield of autologous blood from patients in a pre-donation program initiated to avoid the use of homologous blood. Treatment is indicated in patients with moderate anaemia (PCV approx. 33 to 39%, no iron deficiency) if blood conserving procedures are not available or insufficient either:	19th August, 1994