

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
PL 00006/0337	Eli Lilly and Company Limited	Humulin S Pen	Human Insulin (PRB) 100 iu	For the treatment of patients with diabetes mellitus who require insulin for the maintenance of glucose homeostasis. Humulin is also indicated for the initial control of diabetes mellitus and diabetes mellitus in pregnancy. Pharmacy Medicine	19th September 1997
PL 00006/0338	Eli Lilly and Company Limited	Humulin I Pen	Human Insulin (PRB) 100 iu	See 00006/0337 Pharmacy Medicine	19th September 1997
PL 00006/0339	Eli Lilly and Company Limited	Humulin M1 Pen	Human Insulin (PRB) 100 iu	See 00006/0337 Pharmacy Medicine	19th September 1997
PL 00006/0340	Eli Lilly and Company Limited	Humulin M2 Pen	Human Insulin (PRB) 100 iu	See 00006/0337 Pharmacy Medicine	19th September 1997
PL 00006/0341	Eli Lilly and Company Limited	Humulin M3 Pen	Human Insulin 100 iu	See 00006/0337 Pharmacy Medicine	19th September 1997
PL 00006/0342	Eli Lilly and Company Limited	Humulin M4 Pen	Human Insulin (PRB) 100 iu	See 00006/0337 Pharmacy Medicine	19th September 1997
PL 00006/0343	Eli Lilly and Company Limited	Humulin M5 Pen	Human Insulin 100 iu	See 00006/0337 Pharmacy Medicine	19th September 1997
PL 00012/0282	May & Baker Limited	Maalox Direct Compression Tablets	Aluminium Hydroxide 400 mg Magnesium Hydroxide 400 mg	Antacid therapy for the relief of gastritis, heartburn and gastric hyperacidity. General Sales List	8th September 1997
PL 00014/0565	The Boots Company Plc	Nirolex Day Cold and Flu Comfort	Paracetamol 3.333 wv Pholcodine .033 wv Pseudoephedrine Hydrochloride .200 wv	For the relief of the symptoms of colds and influenza. For oral administration. Pharmacy Medicine	17th September 1997
PL 00019/0132	Warner Lambert (UK) Ltd.	Epanutin Capsules 100 mg	Phenytoin Sodium	Control of Tonic-Clonic Seizures (Grand Mal epilepsy), Partial (focal including temporal Lobe) seizures or a combination of these and the prevention and treatment of seizures occurring during or following neurosurgery and/or severe head injury. Epanutin has also been employed in the treatment of Trigeminal Neuralgia but it should only be used as second line therapy if carbamazepine is ineffective or patients are intolerant to carbamazepine. Prescription Only Medicine	15th September 1997
Product Licence Number	Company Name	Product Name	Active Ingredients	Indications	Date of Authorisation
00019/0151	Warner Lambert (UK) Ltd	Anugestic HC Cream	Zinc Oxide EP 12.35 gm Balsam Peru EP 1.85 gm Benzyl Benzoate EP 1.2 gm Pramoxine Hydrochloride USP 1.0 gm Bismuth Oxide HSE 0.875 gm Hydrocortisone Acetate EP 0.5 gm	Anugestic HC cream provides antiseptic, astringent, emollient and decongestant properties. In addition hydrocortisone exerts an anti-inflammatory effect. Pramoxine is a rapidly acting local anaesthetic. The cream may be used to provide lubrication for suppositories. Anugestic HC cream is indicated for the comprehensive symptomatic treatment of severe and acute discomfort or pain associated with internal and external haemorrhoids, and pruritus ani. Prescription Only Medicine (See PL/00019/0151) Prescription Only Medicine	30th September 1997
00019/0152	Warner Lambert (UK) Ltd	Anugestic HC Suppositories	Pramoxine Hydrochloride USP 27 mg Hydrocortisone Acetate EP 5 mg Benzyl Benzoate EP 33 mg Bismuth Oxide HSE 24 mg Bismuth Subgallate 1980 BP 59 mg Balsam Peru EP 49 mg Zinc Oxide EP 296 mg	See PL/00019/0151 Prescription Only Medicine	30th September 1997
00030/0092	Novartis Consumer Health UK Ltd	Eurax Cream	Crotamiton BP 10.0% w/w	For the relief of Itching and skin irritation caused by for example sunburn, dry eczema, itchy dermatitis, allergic rashes, hives, nettle rash, chickenpox, insect bites and stings, heat rashes and personal itching. Treatment of scabies. General Sales List	1st September 1997
00030/0093	Novartis Consumer Health UK Ltd	Eurax HC Cream	Crotamiton BP 10.00 w/w Hydrocortisone BP 0.25 w/w	Relief of inflammation and pruritus associated with irritant contact dermatitis, allergic contact dermatitis, insect bite reactions and mild to moderate eczema. Pharmacy Medicine	1st September 1997
00030/0094	Novartis Consumer Health UK Ltd	Eurax Hydrocortisone Cream	Crotamiton BP 10.00 w/w Hydrocortisone BP 0.25 w/w	Eczema and dermatitis of all types including atopic eczema, photodermatitis, otitis externa, primary irritant and allergic	1st September 1997