

Product Licence Number	Company Name	Product Name	Active Ingredients	Indications	Date of Authorisation
8142/0005	Norton (Waterford) Limited	Beclomethasone Dipropionate Inhaler 250 ug or Beclazone 250 Inhaler	Beclomethasone Dipropionate (as propellant 11 Solvate) HSE 250.0 ug	Prescription Only Medicine (i) Beclomethasone Dipropionate Inhaler 250 ug is indicated for those asthmatic patients who have been shown to require high doses (greater than 800 micrograms - 1,000 micrograms daily) of Beclomethasone Dipropionate BP to control their symptoms. (ii) It may also be indicated for those patients whose asthma is no longer controlled by maximum maintenance doses of bronchodilators and Beclomethasone Dipropionate 50 ug or 100 ug Inhaler. Some patients with severe asthma require oral corticosteroid therapy in addition to Beclomethasone Dipropionate Inhaler 50 ug or 100 ug for the adequate control of their symptoms. Many of these patients may, on transfer to Beclomethasone Dipropionate Inhaler 250 ug, be able to reduce significantly or eliminate their requirement for additional oral corticosteroids.	28th May 1993
8223/0172	Discpharm Limited	Estraderm TTS	Oestradiol Valerate 4.0 mg	Prescription Only Medicine Oestrogen replacement therapy for patients with disorders due to natural or surgically induced menopause eg vasomotor symptoms (hot flushes and nocturnal sweating), Urogenital conditions such as Atrophic Vaginitis/Vulvitis and/or Atrophic Urethritis and Trigonitis. Oestrogen therapy must not be used in patients with an intact uterus unless an appropriate dose of Progestogen is administered for twelve days per month. Mode of action: Oestrogen substitution effectively prevents the characteristic symptomatic, metabolic and trophic changes associated with loss of ovarian function due to natural or surgical menopause. Estraderm TTS is a dosage form designed to achieve release of 17B-Oestradiol, via intact skin to the systemic circulation for several days at a low rate.	18th August 1993
8381/0004	Sigma-Tau Industrie Farmaceutiche Riunite SpA	Elcarn Oral Single-Dose 1G	L-Carnitine Inner Salt HSE 1.0 GM	Prescription Only Medicine Indicated in the treatment of primary and secondary carnitine deficiency in adults and children over 12 years of age.	26th May 1993
8387/0015	Hogens Limited	Salmon Calcitonin 200 IU	Salmon Calcitonin BP 200.00 IU	Prescription Only Medicine For the <i>Short Term</i> treatment of: 1. Paget's Disease of Bone. 2. Advancing Osteolytic hypercalcaemia of Malignancy. 3. Pain associated with advanced Metastatic Bone Cancer. The use of Salmon Calcitonin has been reported to be beneficial in the relief of pain in some patients with advanced Bone Cancer. 4. Postmenopausal Osteoporosis. Studies based on total body calcium determinations have indicated that Salmon Calcitonin may be effective in the prevention of progressive loss of bone mass in the treatment of Postmenopausal Osteoporosis.	13th August 1993
10382/0060	Wholesale PI Limited	Ventolin Inhaler	Salbutamol 0.1 mg	Prescription Only Medicine Ventolin Inhaler is indicated both for the treatment and prophylaxis of bronchial asthma and also for the treatment of other conditions such as bronchitis and emphysema with associated reversible airways obstruction. Because ventolin inhaler is long acting it is ideally suited for routine maintenance therapy in chronic asthma and chronic bronchitis. The inhaler drug delivery system using salbutamol in microgram dosage avoids the skeletal muscle tremor sometimes associated with oral therapy. When necessary to relieve attacks	13th August 1993