

Product Licence Number	Company Name	Product Name	Active Ingredients	Indications	Date of Authorisation
00530/0482	Norton Healthcare Limited	Calcicard CR Tablets 90 mg. Angiozem CR Tablets 90 mg	Diltiazem Hydrochloride 90-000 mg	is being treated with levodopa alone or levodopa and peripheral decarboxylase inhibitor. Selegiline in conjunction with levodopa treatment is particularly indicated in patients during maximal levodopa treatment, develop on-off symptoms or other dyskinesias. Prescription Only Medicine	26th July 1995
00530/0483	Norton Healthcare Limited	Angiozem CR Tablets 120 mg. Calcicard CR Tablets 120 mg	Diltiazem Hydrochloride 120-000 mg	Angina pectoris and mild to moderate hypertension. Prescription Only Medicine See PL/00530/0482.	26th July 1995
00530/0502	Norton Healthcare Limited	Temazepam Tablets 10 mg	Temazepam 10.000 mg	Temazepam Tablets are indicated for: (1) The short-term treatment of insomnia only when it is severe, disabling, or subjecting the individual to extreme stress, especially for those patients in whom the persistence of a hypnotic effect would be undesirable. (2) The premedication before minor surgical and investigative procedures particularly when hospital admission is not essential. Prescription Only Medicine	16th October 1995
00530/0503	Norton Healthcare Limited	Temazepam Tablets 20 mg	Temazepam 20.000 mg	See PL/0530/0502 Prescription Only Medicine	16th October 1995
00790/0116	Clonmel Healthcare Limited	Selegiline tablets 5 mg	Selegiline Hydrochloride 5.000 mg	Selegiline tablets are indicated for the treatment of Parkinson's disease, or symptomatic Parkinsonism. Selegiline may be used alone in early Parkinson's disease to delay the need for levodopa (with or without decarboxylase inhibitor). Selegiline may also be used as an adjunct to levodopa therapy (with or without decarboxylase inhibitor). Prescription Only Medicine	17th October 1995
03433/0175	Farmitalia Carlo Erba Limited	Cystrin 1 mg/ml Syrup	Oxbutynin Hydrochloride USP 1-02 mg equivalent to anhydrous oxbutynin HCl 1-0 mg	For urinary incontinence, urgency and frequency in unstable bladder conditions due either to idiopathic detrusor instability or neurogenic bladder disorders [Detrusor Hyperreflexia] in conditions such as Spina Bifida and Multiple Sclerosis. Children over 5 years of age: In addition to neurogenic bladder disorders this may be used in nocturnal enuresis in conjunction with non-drug therapy where this alone, or in combination with other drug treatment has failed. Prescription Only Medicine	18th July 1995
3787/0348	Swingward Limited, t/a Spectrum Marketing	Imuran 25 mg Tablets/Azathioprine 25 mg Tablets	Azathioprine 25-000 mg	Used as immunosuppressant antimetabolite. Prescription Only Medicine	12th October 1995
3787/0359	Swingward Limited t/a Spectrum	Intal Inhaler	Sodium Cromoglycate 5-000 mg	The treatment of bronchial asthma, including the prevention of exercise-induced asthma. Prescription Only Medicine	12th October 1995
3787/0360	Swingward Limited t/a Spectrum Group	Bisoprolol 10 mg Tablets	Bisoprolol Fumarate 10-000 mg	1. Management of hypertension. 2. Management of angina pectoris. Prescription Only Medicine	5th October 1995
3787/0361	Swingward Limited t/a Spectrum	Serevent Diakhler	Salmeterol Xinafoate 72-500 mg	Treatment of reversible airways obstruction (including nocturnal asthma, and prevention of exercise-induced bronchospasm). Prescription Only Medicine	17th October 1995
3787/0362	Swingward Limited t/a Spectrum Marketing	Becloforte Inhaler/Beclomethasone 250 Inhaler	Beclomethasone Dipropionate 250-000 ug	Asthmatic patients who require high doses (greater than 800 micrograms to 1000 micrograms daily) of Beclomethasone Dipropionate to control their symptoms. Prescription Only Medicine	25th September 1995
3787/0365	Swingward Limited t/a Spectrum	Tarivid 200 mg Tablets	Ofloxacin 200-000 mg	Upper and lower urinary tract infections; lower respiratory tract infections; uncomplicated urethral and cervical gonorrhoea; non-gonococcal urethritis and cervicitis. Prescription Only Medicine	29th September 1995
04515/0077	Faulding Pharmaceuticals Plc	Sterile Dobutamine Hydrochloride Concentrate 250 mg in 20 ml	Debutamine Hydrochloride USP 12.5 mg	Indicated for adults who: 1. Require inotropic support in the treatment of low output cardiac failure associated with organic heart disease, myocardial infarction, open heart surgery cardiomyopathies, septic shock and cardiogenic shock. 2. It can increase or maintain cardiac output during positive end expiratory pressure (PEEP) ventilation. Prescription Only Medicine	26th September 1995
04515/0080	Faulding Pharmaceuticals Plc	Morcap SR Capsules 20 mg	Morphine Sulphate BP 20-0 mg	For the prolonged relief of chronic, moderate to severe pain. For use in patients who require repeated dosing with potent opioid	7th July 1995