

<i>Product Licence Number</i>	<i>Company Name</i>	<i>Product Name</i>	<i>Active Ingredients</i>	<i>Indications</i>	<i>Date of Authorisation</i>
12724/0216	Regent-GM Laboratories Limited	Piroxicam Capsules 10 mg	Piroxicam 10.000 mg	Prescription Only Medicine Non-steroidal anti-inflammatory agent indicated in the treatment of conditions requiring anti-inflammatory and/or analgesic activity. These include: Rheumatoid arthritis, Osteoarthritis (arthrosis, degenerative joint disease), Ankylosing spondylitis Acute musculoskeletal disorders, and Acute gout.	22nd December, 1998
12724/0217	Regent-GM Laboratories Limited	Piroxicam Capsules 20 mg	Piroxicam 20.000 mg	Prescription Only Medicine Same as in PL 12724/0216	22nd December, 1998
13442/0003	Biomet Merck Ltd	Septopal Chains	Gentamicin Sulphate (per head) 7.5 mg equivalent to Gentamicin base 4.5 mg	Prescription Only Medicine Short and longer term therapy in bone infection, e.g. osteomyelitis, infected pseudoarthroses, infected osteosynthesis. Short term preventative treatment of potentially infected bone injuries. Short term prevention and therapy of soft tissue infections associated with abdominoperineal resections, operations on the small or large bowel. Other therapeutic indications for use include bacterial peritonitis, cholecystectomies, infective fistulae, infected vascular grafts, soft tissue abscesses.	31st December, 1998
13249/0020	Johnson & Johnson MSD Consumer Pharmaceuticals	Imodium plus	Loperamide Hydrochloride 2.000 mg Simethicone 125.000 mg	Pharmacy Medicine For the symptomatic treatment of acute diarrhoea in adults and adolescents over 12 years when acute diarrhoea is associated with gas-related abdominal discomfort including bloating, cramping or flatulence.	16th January, 1999
13442/0004	Biomet Merck Limited	Septopal Minichains	Gentamicin Sulphate 2.800 mg	Prescription Only Medicine Short term and longer term administration in bone infection, e.g. osteomyelitis, infected pseudoarthroses, infected osteosynthesis. Short term preventative treatment of potentially infected bone injuries. Surgical fields for which this has been expressly developed are: hand and foot surgery, face and jaw surgery and paediatrics.	31st December, 1998
14069/0068	Denfleci International Limited	Trusopt 2% Ophthalmic Solution	Dorzolamide Hydrochloride 22.260 mg	Prescription Only Medicine The treatment of elevated intra-ocular pressure.	15th December, 1998
15361/0038	P.I.E. Pharma Limited	Fluticasone Propionate Accuhaler 100 mcg Flixotide Accuhaler 100 mcg	Fluticasone Propionate 100.000 mcg	Prescription Only Medicine The management of Asthma.	15th January, 1999
15361/0039	P.I.E. Pharma Limited	Fluticasone Propionate Accuhaler 250 mcg Flixotide Accuhaler 250 mcg	Fluticasone Propionate 250.000 mcg	Prescription Only Medicine The management of Asthma.	15th January, 1999
15361/0040	P.I.E. Pharma Limited	Fluticasone Propionate Accuhaler 500 mcg, Flixotide Accuhaler 500 mcg	Fluticasone Propionate 500.000 mcg	Prescription Only Medicine Asthma.	14th January, 1999
15361/0099	P.I.E. Pharma Limited	Sertraline 50 mg Tablets Aremis 50 mg Tablets	Sertraline 50.000 mg Sertraline Hydrochloride 55.950 mg	Prescription Only Medicine Treatment of symptoms of depressive illness.	23rd December, 1998
15361/0100	P.I.E. Pharma Limited	Sertraline 100 mg Tablets Aremis 100 mg Tablets	Sertraline 100.000 mg	Prescription Only Medicine Treatment of symptoms of depressive illness.	23rd December, 1998
15722/0042	Boehringer Mannheim UK Limited	Torem 50 Tablets	Torsemide 50.000 mg	Prescription Only Medicine Oedema due to renal failure and nephrotic syndrome.	9th November, 1998
15814/0108	OPD Laboratories Limited	Arthrotec 50 Tablets	Diclofenac Sodium 50.000 mg Misoprostol 200.000 mcg	Prescription Only Medicine 1. The treatment of osteoarthritis and rheumatoid arthritis. 2. The prophylaxis of NSAID-induced gastric and duodenal ulceration.	13th January, 1999
15814/0117	OPD Laboratories Limited	Pergolide Tablets 1 mg Celance 1 mg Tablets	Pergolide 1.000 mg	Prescription Only Medicine The management of Parkinson's Disease.	15th December, 1998
15814/0122	OPD Laboratories Limited	Carduran 4 mg Tablets Doxazosin Tablets 4 mg	Doxazosin Mesilate 4.860 mg	Prescription Only Medicine Hypertension.	8th January, 1999
15819/0039	Loxex Synthelabo UK & Ireland Limited	Cystrin 3 mg Tablets	Oxybutynin Hydrochloride 3.060 mg	Prescription Only Medicine 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. In addition, for children over 5 years of age, oxybutynin may be used	30th September, 1998