

Product Licence Number	Company Name	Product Name	Active Ingredients	Indications	Date of Authorisation
06745/0097	Pasteur Merieux MSD Ltd	HB-Vax II Paediatric	Hepatitis B Surface Antigen 5.000 mcg	Prescription Only Medicine This vaccine is indicated for active immunisation against hepatitis B virus infection caused by all known subtypes in subjects of all ages considered at risk of exposure to hepatitis B virus. Groups identified at increased risk of infection: Children frequently receiving blood products. Children in haemodialysis and oncology units, children suffering from thalassaemia, sickle cell anaemia, haemophilia, and children receiving frequent blood transfusions or clotting factor concentrates, organ transplants. Infants born of mothers who are HBV carriers. Children residents of institutions. Children residents of institutions for mentally handicapped. Travellers' children to areas with a high endemicity of HBV. Children originating from areas with a high endemicity of HBV. Adoptees, immigrants and refugees. Others: Children through their personal lifestyle may be exposed to HBV. Household contacts of any of the above groups and contacts with acute or chronic HBV infection. Nevertheless, the recommendations should be adjusted in line with national vaccination policies since in some countries generalisation of vaccination is highly recommended.	1st January, 1999
06745/0098	Pasteur Merieux MSD Ltd	HBVax II 40	Hepatitis B Surface Antigen 40.000 mcg	Prescription Only Medicine This vaccine is indicated for dialysis and predialysis patients, for the active immunisation against hepatitis B virus infection caused by all known subtypes in subjects of all ages considered at risk of exposure to HBV.	1st January, 1999
08747/0223	Chemilines Limited	Pharken Tablets 50 mcg Pergolide Tablets 50 mcg	Pergolide 50.000 mcg	Prescription Only Medicine The management of Parkinson's disease.	21st December, 1998
08747/0232	Chemilines Limited	Bisoprolol Fumarate 10 mg Tablets Monocor 10 mg Tablets Soprol 10 mg Tablets	Bisoprolol Fumarate 10.000 mg	Prescription Only Medicine 1. Hypertension. 2. Angina Pectoris.	8th January, 1999
08747/0237	Chemilines Limited	Terbutaline Sulphate 250 mcg Inhaler Bricanyl Inhaler	Terbutaline Sulphate 250.000 mcg	Prescription Only Medicine The relief and prevention of bronchospasm.	21st December, 1998
10256/0367	Stephar (UK) Limited	Combivent Inhaler	Ipratropium Bromide Monohydrate 21.000 mcg Salbutamol Sulphate 120.000 mcg	Prescription Only Medicine The treatment of bronchospasm.	13th January, 1999
10256/0386	Stephar (UK) Limited	Froben SR Capsules	Flurbiprofen 200.000 mg	Prescription Only Medicine The treatment of intestinal amoebiasis.	6th January, 1999
10380/0214	Swinghope Limited	Gabapentin 100 mg Capsules Neurontin 100 Capsules	Gabapentin 100.000 mg	Prescription Only Medicine Epilepsy.	13th January, 1999
10380/0215	Swinghope Limited	Gabapentin 300 mg Capsules Neurontin 300 Capsules	Gabapentin 300.000 mg	Prescription Only Medicine Epilepsy.	13th January, 1999
10380/0216	Swinghope Limited	Gabapentin 400 mg Capsules Neurontin 400 Capsules	Gabapentin 400.000 mg	Prescription Only Medicine Epilepsy.	13th January, 1999
10380/0260	Swinghope Limited	Risperdal 2 mg Tablets Risperidone 2 mg Tablets	Risperidone 2.000 mg	Prescription Only Medicine The treatment of schizophrenic psychoses.	8th January, 1999
10380/0261	Swinghope Limited	Risperdal 3 mg Tablets Risperidone 3 mg Tablets	Risperidone 3.000 mg	Prescription Only Medicine The treatment of schizophrenic psychoses.	12th January, 1999
10380/0262	Swinghope Limited	Risperdal 4 mg Tablets Risperidone 4 mg Tablets	Risperidone 4.000 mg	Prescription Only Medicine The treatment of schizophrenic psychoses.	8th January, 1999
10380/0270	Swinghope Limited	Permax 1 mg Tablets Pergolide Tablets 1 mg	Pergolide 1.000 mg	Prescription Only Medicine Parkinson's Disease.	13th January, 1999
10380/0282	Swinghope Limited	Amlodipine Tablets 10 mg	Amlodipine 10.000 mg	Prescription Only Medicine 1. Hypertension. 2. Angina Pectoris.	8th January, 1999
10380/0286	Swinghope Limited	Loratidine 10 mg Tablets Clarityne Tablets	Loratidine Micronised 10.000 mg	Prescription Only Medicine The relief of symptoms of allergic rhinitis and urticaria.	8th January, 1999
10383/0533	Primecrown Limited	Simvastatin 20 mg Tablets	Simvastatin 20.000 mg	Prescription Only Medicine Hypercholesterolaemia.	19th January, 1999
10383/0581	Primecrown Limited	Pergolide Tablets 50 mcg Nopar 50 mcg Tablets	Pergolide .050 mg	Prescription Only Medicine Parkinson's Disease.	8th January, 1999