

Product Licence Number	Company Name	Product Name	Active Ingredients	Indications	Date of Authorisation
				Where used together, these products should be administered with separate syringes into separate sites. For known non-responders to vaccine, a booster dose of vaccine can be considered for simultaneous administration with Hepatitis B Immunoglobulin. Indications for the use of this product are as follows: i) Parenteral Exposures: Any subcutaneous or other injections, needleprick or blood transfusion. Other indications are skin breaking bites by infective people and cases where there is clear evidence of contamination of a wound or of the conjunctiva. Simultaneous administration of the first dose of a licensed Hepatitis B vaccine may be considered for administration into a separate site. ii) Sexual Exposure: It may be administered to recent sexual contacts of diagnosed Hepatitis B cases. iii) Newborns: It is indicated for a neonate where the mother has had acute Hepatitis B in the last trimester of pregnancy, or who is an HBsAg positive carrier or who is an HBsAg-Positive carrier without HBc markers (or where the HBsAg status has not been determined). A single dose of immunoglobulin is given within 4 hours of birth combined with vaccine into a separate site. The vaccine course is then completed according to the Manufacturer's instructions.	
04416/0284	Lagap Pharmaceuticals Limited	Modisal 60 XL	Isosorbide 5-Mononitrate 60.000mg	Pharmacy Medicine Prophylactic treatment of angina pectoris.	5th March 1998
04423/0238	Doncaster Pharmaceuticals Group Limited	Naprosyn 250mg Tablets/ Naproxen 250mg Tablets	Naproxen 250.000mg	Prescription Only Medicine Rheumatoid arthritis and dysmenorrhoea.	1st June 1998
04423/0239	Doncaster Pharmaceuticals Group Limited	Naprosyn LE 500mg Tablets/ Naproxen 500mg Tablets	Naproxen 500.000mg	Prescription Only Medicine Rheumatoid arthritis and dysmenorrhoea.	1st June 1998
04423/0258	Doncaster Pharmaceuticals Group Limited	Tritudan Suspension	Terfenadine 30.000mg	Prescription Only Medicine Allergic conditions responsive to antihistamines.	1st June 1998
04423/0276	Doncaster Pharmaceuticals Group Limited	Glucobay 50mg Tablets/ Acarbose 50mg Tablets (Spain)	Acarbose 50.00mg	Prescription Only Medicine Non-insulin dependent diabetes mellitus.	3rd June 1998
04423/0290	Doncaster Pharmaceuticals Group Limited	Risperdal 1mg Tablets/ Risperidone 1mg Tablets	Risperidone 1.000mg	Prescription Only Medicine For the treatment of acute and chronic schizophrenic psychoses.	1st June 1998
04515/0084	Faulding Pharmaceuticals Plc	Bleomycin for Injection	Bleomycin Sulphate 15000.000iu	Prescription Only Medicine 1 Squamous cell carcinoma affecting the mouth nasopharynx and paranasal sinuses, larynx, oesophagus, external genitalia, cervix or skin. Well-differentiated tumours usually respond better than anaplastic ones. 2 Hodgkin's disease and other malignant lymphomas including mycosis fungoides. 3 Testicular teratoma. 4 Malignant effusions of serous cavities. 5 Secondary indications in which bleomycin has been shown to be of some value (alone or in combination with other drugs) include metastatic malignant melanoma, carcinoma of the thyroid, lung and bladder.	29th May 1998