

| <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> |
|-------------------------------|-----------------------------|-------------------------|---|---|------------------------------|
| 06464/0710                    | Waymade Plc                 | Nivemycin Tablets 500mg | Neomycin Sulphate 550.000mg                   | Prescription Only Medicine<br>See PL06464/0709  | 11th January 1999            |
| 06464/0711                    | Waymade Plc                 | Cortistab Tablets 5mg   | Cortisone Acetate UF PDR 5 Omg                | Prescription Only Medicine<br>Replacement therapy for such condition as Addison's disease, primary or secondary adrenal insufficiency or congenital adrenal hyperplasia.  | 11th January 1999            |
| 06745/0087                    | Pasteur Merieux MSD Limited | Stamari                 | Yellow Fever Virus 17D/AB237 Strain 1000.000u | Prescription Only Medicine<br>Prevention of yellow fever, the vaccination is recommended for<br>* Adults and children aged 9 months and over, travelling through or living in infected areas and those travelling outside urban areas of countries in the yellow fever endemic zone, (even if these countries have not officially reported the disease and do not require evidence of immunisation on entry). * Travellers requiring an International Certificate of Vaccination for entry into a country * Laboratory workers handling infected material. In order to comply with vaccine regulation and to be officially recognised, Stamari® vaccination must be administered at a designated vaccination centre and registered on an International Certificate. The International Certificate is valid for ten years from the tenth day after immunisation and immediately after re-immunisation. Vaccination for children aged under 9 months is not recommended   | 13th October 1998            |
| 06745/0096                    | Pasteur Merieux MSD Limited | HB-Vax II               | Hepatitis B Surface Antigen 10.000mcg         | Prescription Only Medicine<br>This vaccine is indicated for active immunisation against hepatitis B virus infection caused by all known sub types in subjects of all ages considered at risk of exposure to hepatitis B virus. Groups identified at increased risk of infection: Health care personnel, Oral surgeons, dentists, physicians and surgeons nurses, dental hygienists, paramedical personnel in close contact with patients, staff in haemodialysis, haematology and oncology units, laboratory personnel handling blood and other clinical specimens, emergency and first aid workers, ambulance staff, blood bank and plasma fractionation workers, cleaning staff in hospitals handling waste, chiropodists, morticians and embalmers. Patients frequently receiving blood products. Patients in haemodialysis and oncology units, patients suffering from thalassaemia, sickle cell anaemia, liver cirrhosis, haemophilia, and patients receiving frequent blood transfusion or clotting factor concentrates, patients receiving organ transplants. Personnel collecting, sorting out, handling the specific waste and household rubbish. Personnel and residents of institutions. Persons with frequent and/or close contacts with high risk groups prisoners and prison staff, residents and staff of institutions for mentally handicapped. Personnel at increased risk due to their sexual behaviour. Persons with multiple sexual partners, patients with a Sexually Transmitted Disease (STD), persons seeking treatment for an STD, prostitutes and male homosexuals. Illicit users of addictive injectable drugs. Travellers to areas with a high endemicity of HBV. Persons originating from areas with a high endemicity of HBV. Adoptees, immigrants and refugees. Others: police personnel, fire brigade personnel, armed forces personnel and anybody who through their work or 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             |