Formulation: Each immunizing dose contains inactivated and purified, freeze-dried rabies vaccine (Wistar strain rabies PM/WI 38-1503-3m) produced on vero cell line immunizing dose. It also contains maltose up to 1 immunizing dose, human plasma albumin up to 1 immunizing dose 4%, sodium chloride solution (diluents) 0.5mL.

Such that the protective power is > 2.5 IU before and after heating for 1 month at 37°C.

INDICATIONS: Pre-Exposure: For the prevention of rabies in subjects at a high risk of exposure. All subjects at a permanent risk. eg, diagnostic, research and production laboratory staff working on rabies virus, should be vaccinated. A serological test is recommended every 6 months. A booster injection should be administered when the antibody titer is below the level considered to guarantee protection: 0.5IU/mL.

The following categories should be vaccinated given the fregamekeepers, hunters, forest rangers, slaughterhouse personnel, cavers, taxidermists; subjects exposed to enzootic areas eg, children, adults and travellers visiting these areas. Post-Exposure: After confirmed or suspected exposure, vaccination must be started immediately at the slightest risk of contamination with rabies. It must be performed in a rabies treatment center. The treatment is adapted to the type of wound and the status of the animal.

DOSEAGE & ADMINISTRATION: The vaccination schedule should be adapted according to the circumstances of the vaccination and the subject’s rabies immune status.

Preventive or Pre-Exposure Vaccination: Primary Vaccination: 3 injections on days 0, 7 and 28. Booster injection 1 year later then every 5 years.

The injection scheduled on day 28 may be administered on day 21.

“Curtative” Vaccination (Prevention of Rabies After Confirmed or Suspected Exposure): First-Aid Treatment: The treatment of wounds is very important must be performed promptly after the bite. It is recommended firstly to wash the wound with large quantities of water and soap or detergent and then apply 70% alcohol, tincture of iodine or a 0.1% quaternary ammonium solution (provided that no soap remains as these 2 products neutralize each other). Curtative vaccination must be administered under medical supervision and only in a rabies treatment center.

Vaccination of Non-Immunized Subjects: The dosage is the same for adults and children. It includes five 0.5mL injections on days 0, 3, 7, 14 and 28. In the case category III exposure, rabies immunoglobulins must be administered in association with the vaccine. Additional passive immunization on day 0 is required: Human rabies immunoglobulin (HRI): 20 IU/kg of body weight; equine immunoglobulin 40 IU/kg of body weight. If possible, Verorabies should be injected on the side opposite the immunoglobulin administration sites. In enzootic areas, the severity of certain exposures due to the severity of the lesions and/or location (proximity of the central nervous system), a late consultation or immunodeficiency of the subject may justify, depending on the case, 2 injections on day 0.

Vaccination of Subjects Already Immunized: Vaccination administered <5years previously (cell culture rabies vaccine): 2 injections on days 0 and 3; >5 years previously or incomplete of immunoglobulins, if required. In practice, if the last booster dose was administered >5 years previously or if the vaccination is incomplete, the vaccine is considered to have as uncertain vaccination status.

Administration: To reconstitute Verorabies, introduce the diluent into the vial powder and shake thoroughly until the powder is completely suspended. The solution should be homogenous, clear and free of any particles. Withdraw the solution in a syringe. Verorabies must be injected immediately after reconstitution and the syringe must be destroyed after use. Verorabies is administered by the IM route only in the deltoid in adults and in the anterolateral region of the thigh muscle in children. Do not inject in the gluteal region.

Contraindications: Pre-Exposure: Severe febrile infection, acute disease, progressive chronic disease (it is preferable to postpone vaccination). Allergy to neomycin, mycobacteria, and the excipients. In patients allergic to the excipients of the vaccine, premedication with antihistamines is appropriate. In the other cases, the vaccine can be used.

Use in pregnancy & lactation: Verorabies has not been the subject of animal teratogenicity studies. In the absence of sufficient human data, it is recommended to postpone pre-exposure vaccination. For the vaccination of patients at high risk of contamination, the benefit/risk ratio must be assessed before administering the injection. In pre-exposure vaccination, due to the severity of the disease, pregnancy is not a contraindication as a general rule, during pregnancy and lactation, it is recommended to always ask the doctor or pharmacist for advice before using a medicinal product.

Warnings: Use with caution on patients with a known allergy to neomycin (present in trace form in the vaccine). Do not inject by the intravenous route make sure that the needle does not enter a blood vessel. Immunoglobulins and rabies vaccine must not be associated in the same syringe or injected at the same site. A serological test (neutralizing antibody assay using the rapid fluorescent focus inhibition test [RFFIT]) must be conducted on persons subject to continuous exposure (every 6 months) and may be conducted every 2-3 years after the booster dose after 1 and 5 years in persons subject to discontinuous exposure according to the assessed exposure risk. For immunodeficient subjects, this may be conducted 2-4 weeks following the vaccination. If the results of the demonstrates an antibody titer <0.5IU/mL a booster injection or an additional injection, for immunodeficient subjects is justified.

Precautions: Inform the doctor in the event of known allergy to neomycin, due to the use of these substances during production. If there is any doubt, do not hesitate to consult the doctor or pharmacist.

Side Effects: As for any active product, Verorabies may induce undesirable effects to a varying degree in certain subjects: Minor local reactions (pain, erythma, edema, pruritus and induration at the injection point); systemic reactions (moderate fever, shivering, faintness, asthma, headaches, dizziness, arthralgia, myalgia, gastrointestinal disorders [nausea abdominal pains]); exceptionally, anaphylactoid reactions, urticaria due to the antigen in the vaccine, which may cause anaphylaxis in the doctor any unwanted and disturbing effect which is not mentioned previously.

Interactions: Corticosteroids and immunosuppressor treatments may interfere with antibody production and cause the vaccination to fail. Therefore, it is preferable to conduct a neutralizing antibody assay 2-4 weeks after the last injection of the vaccine. In order to avoid possible interactions between several medicinal products, any other ongoing treatment should be systematically reported to the doctor or pharmacist.

Storage: Store at temperatures not exceeding 8°C. Protect from light.

Availability: Box of 5’5 & 1’s.

CAUTION: FOODS, DRUGS, DEVICES and COSMETICS ACT prohibit dispensing without prescription.

Manufactured by: JIANGSU YANSHEN BIOLOGICAL TECHNOLOGY STOCK, CO. LTD.
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Imported & Distributed by: SAHAR INTERNATIONAL TRADING INC.
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