

## Rabies Vaccine, Inactivated [Verorab®] Abridged Product Information



**Product:** Rabies vaccine, inactivated (Verorab®)

**Strength:** 0.5 mL Powder and Solvent for Suspension for Intramuscular Injection in prefilled syringe

**Presentation:** Powder in Type 1 glass vial + 0.5 mL of Solvent in Type 1 prefilled glass syringe (Box of 1)

**I:** Rabies vaccine, inactivated For the prevention of rabies in children and adults. It can be used before and after exposure to the rabies virus, as a primary vaccination or as a booster dose. It is administered generally in the anterolateral region of the thigh muscle until the age of 12 months and in the deltoid muscle after this age.

**C:** Hypersensitivity to the active substances or to any of the excipients listed or to polymyxin B, streptomycin, neomycin, or to any antibiotic of the same group, to a previous administration or to any vaccine containing the same components. Vaccination should be postponed in case of febrile or acute diseases. Intradermal route must not be used in the following instances: individuals receiving long term corticosteroid or other immunosuppressive therapy or chloroquine, immunocompromised individuals, and individuals, particularly children, with severe wounds, especially to the head and neck or presenting late for consultation.

**W/P:** Injection schedule recommendation should be followed accordingly. Anxiety related reactions can occur following or even before any vaccination as a psychogenic response to the needle injection thus procedures should be in place to prevent injury. When vaccine is administered to subjects with a known deficiency due to an immunosuppressive illness or a concomitant immunosuppressive treatment, a serological test should be performed 2 to 4 weeks after vaccination. Appropriate medical treatment and supervision must be readily available in case of a rare anaphylactic reaction after vaccine administration, particularly in during post exposure in subjects. Should be administered with caution in subjects with thrombocytopenia or coagulation disorders as intramuscular injection may induce bleeding in these subjects. The potential risk of apnea and need for respiratory monitoring for 48-72 hours should be considered when administering the primary immunization series to premature infants and for those with a previous history or respiratory immaturity. For pregnant, or breastfeeding, consult your healthcare provider before receiving the vaccine.

**Interactions:** Corticosteroids and immunosuppressive treatments may interfere with the production of antibodies and lead to vaccination failure. Rabies immunoglobulin and vaccine must never be combined in the same syringe or administered at the same site. The vaccine should be administered contra laterally to the immunoglobulins administration sites.

**AE:** Allergic reactions, headache, dizziness, nausea, muscular pain, redness or pain at the injection site, fatigue, sudden hearing decrease or loss

**PK/PD:** Rabies vaccine, inactivated (Verorab®) is indicated before and after exposure to the rabies virus, as a primary vaccination or as a booster dose in children and adults. During preexposure vaccination, the serum antibody level  $\geq 0.5$  IU/mL considered as protective by the WHO is achieved after injection of 3 doses at D0, D7, and D28 (or D21). This immunity should be maintained with booster doses. In post exposure treatment of adults exposed to the rabies virus, the serum antibody level exceeded the threshold of 0.5 IU/mL, considered as protective by WHO, from the third injection at D14. For subjects already immunized, the administration of 2 doses 3 days apart post exposure makes it possible to achieve a serum antibody level  $> 0.5$  IU/mL, considered as protective by WHO. The administration of rabies immunoglobulins is not necessary in this case. Slightly lower mean neutralizing antibody titres may be observed when human rabies immunoglobulins (HRIG) or equine rabies immunoglobulins (ERIG) are administered at the same time as the first two doses of rabies vaccine, in accordance with the Zagreb regimen. Toxicity studies in animals (acute, sub acute, and chronic toxicity) do not indicate any toxic effects or target organ toxicity.

Reference: Rabies vaccine, inactivated (Verorab®). Philippines Prescribing Information

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