

## **Prescribing Information: Verorab powder and solvent for suspension for injection (Rabies vaccine, inactivated)**

Please refer to the Summary of Product Characteristics (SmPC) before prescribing.

**Presentation:** A single dose vial of powdered vaccine and pre-filled syringe of solvent for suspension for injection. After reconstitution with 0.5 mL solvent, 1 vial contains 3.25 International Units of rabies virus, W1STAR Rabies PM/WI38 1503-3M strain (inactivated).

**Indication:** Verorab is indicated for pre-exposure and post-exposure prophylaxis of rabies in all age groups. Verorab should be used according to official recommendations.

**Dosage and Administration:** The recommended dose for both children and adults is 0.5 mL of reconstituted vaccine intramuscularly (IM) in the anterolateral region of the thigh muscle in infants and young children and in the deltoid muscle in older children and adults, or 0.1 mL of reconstituted vaccine intradermally (ID) in the upper arm or the forearm. Do not inject in the buttocks region. Do not inject via the intravascular route. **Pre-exposure prophylaxis:** For primary pre-exposure immunisation, individuals can be vaccinated according to one of the vaccination schedules presented in below table and according to local official recommendations when available:

	D0	D7	D21 or D28
Intramuscular route (0.5 mL per dose)			
Three-dose regimen IM route - 0.5 mL	1 dose	1 dose	1 dose
One-week regimen <sup>a</sup> IM route - 0.5 mL	1 dose	1 dose	
Intradermal route (0.1 mL per dose)			
One-week regimen <sup>a</sup> ID route - 0.1 mL	2 doses <sup>b</sup>	2 doses <sup>b</sup>	

a - This regimen should not be used for immunocompromised individuals (see subsection "Immunocompromised individuals")

b - One injection in each arm (for adults and children) or each anterolateral thigh (infants and toddlers)

For individuals at continued risk, booster doses should be given in line with official recommendations. Please see SmPC for recommended official guidelines. **Post-exposure prophylaxis:** Post-exposure prophylaxis should be initiated as soon as possible after suspected exposure to rabies. In all cases, proper wound care (careful washing of all bites and scratches with soap or detergent and copious amounts of water and/or virucidal agents) must be performed immediately or as soon as possible after exposure. It must be performed before administration of vaccine or rabies immunoglobulins, when they are indicated. **Post-exposure prophylaxis of immunised and non-immunised individuals:** Post-exposure prophylaxis is recommended for both immunised and non-immunised individuals. Please see SmPC for recommended official guidelines.

**Special Populations: Immunocompromised individuals:** For pre-exposure prophylaxis a 3-dose regimen should be used as per the regimen above and serology testing for neutralising antibodies should be performed 2 – 4 weeks following the last dose to assess the possible need for an additional dose of the vaccine. For post-exposure prophylaxis, a complete vaccine regimen should be administered. Please see SmPC for full dosage instructions.

**Contraindications:** **Pre-exposure prophylaxis:** Hypersensitivity to the active substance(s) or to any of the excipients, to polymyxin B, to streptomycin, to neomycin

(present as traces in the vaccine) or to any antibiotic of the same class, or to a previous administration, or to any vaccine containing the same components. Vaccination should be postponed in case of febrile or acute diseases. **Post-exposure prophylaxis:** Given the always-fatal outcome of the declared rabies infection, there are no contraindications to post-exposure vaccination.

**Warnings and Precautions:** As with all vaccines, Verorab may not protect 100% of vaccinated individuals. **Prior to immunisation:** Injection-schedule recommendations should be followed scrupulously. The need for serological tests (to assess seroconversion in individuals) should be determined in accordance with official recommendations. When the vaccine is administered in individuals with known immunodeficiency, due to an immunosuppressive disease or a concomitant immunosuppressive treatment (including corticosteroids), blood tests must be performed 2 – 4 weeks after vaccination to ensure that a protective immunising response was obtained. In case of post-exposure vaccination, a complete vaccination regimen must be administered. Rabies immunoglobulin must also be administered concomitantly with the vaccine in case of any category II or III exposure (see SmPC for full details). As with all injectable vaccines, appropriate medical treatment and supervision must be readily available in case of a rare anaphylactic reaction after vaccine administration, particularly in case of post-exposure in individuals with a known hypersensitivity to polymyxin B, to streptomycin, to neomycin or to any antibiotic of the same class. **Administration precautions:** Do not inject via the intravascular route – make sure the needle does not penetrate a blood vessel. As with all injectable vaccines, Verorab should be administered with caution in individuals with thrombocytopenia or coagulation disorders as intramuscular injection may induce bleeding in these individuals. Anxiety-related reactions, including vasovagal reactions (syncope), hyperventilation or stress-related reactions can occur following, or even before, any vaccination as a psychogenic response to the needle injection. This can be accompanied by several neurological signs, such as transient visual disturbance and paraesthesia. It is important that procedures are in place to avoid injury from faints. The tip caps of the pre-filled syringes without attached needle contain a natural rubber latex derivative, which may cause severe allergic reactions in latex sensitive individuals. **Paediatric population:** The potential risk of apnoea with the need for respiratory monitoring for 48 – 72 h must be carefully taken into account when administering the primary vaccination doses in very premature infants (born at 28 weeks gestation or less) and particularly in those with a history of respiratory immaturity. **Excipients of known effect:** Verorab contains 4.1 µg phenylalanine per 0.5 mL dose which is equivalent to 0.068 µg/kg for a 60 kg person. Phenylalanine may be harmful for people with phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly. Verorab contains less than 1 mmol of potassium (39 mg) and less than 1 mmol of sodium (23 mg) per dose, that is to say essentially 'potassium-free' and 'sodium-free'.

**Interactions:** Immunosuppressive treatments, including long-term systemic corticosteroid therapy, may interfere

with the production of antibodies and lead to vaccination failure. It is therefore recommended to perform a serological test 2 – 4 weeks after vaccination (see SmPC). Verorab may be administered concomitantly with a Vi polysaccharide typhoid vaccine during the same vaccination visit, using two different injection sites. Rabies immunoglobulins or any other product and the rabies vaccine must never be combined in the same syringe or injected into the same site (see SmPC). Given that rabies immunoglobulins interfere with the development of the immune response to the rabies vaccine, the recommendations for administration of rabies immunoglobulins should be strictly followed.

**Fertility, pregnancy and lactation:** Data on the use of Verorab in pregnant women are limited. Animal developmental and reproductive toxicity studies have not been conducted with this vaccine. Pre-exposure prophylaxis: Given the seriousness of the disease, vaccination should be given to pregnant women only if clearly needed and following an assessment of the risks and benefits, in compliance with the usual vaccination schedule. Post-exposure prophylaxis: Given the seriousness of the disease, the vaccine can be administered during pregnancy. It is unknown whether Verorab is excreted in human milk. No risk has been identified and is anticipated for infants receiving breast milk. Verorab can be administered to breast-feeding women following an assessment of the risks and benefits.

**Adverse Reactions:** Very common: *Adults:* headache, myalgia, injection site pain (IM & ID use), injection site

erythema (ID use), malaise. *Paediatric population:* headache, myalgia, injection site pain (IM & ID use), injection site erythema (ID use), injection site swelling (ID use), malaise, irritability / inconsolable crying & somnolence (in infants/young children). Common: *Adults:* lymphadenopathy, injection site erythema (IM use), injection site pruritus (IM & ID use), injection site swelling (IM & ID use), injection site induration (IM use), influenza-like syndrome, fever. *Paediatric population:* lymphadenopathy, insomnia (in infants/young children), injection site erythema (IM use), injection site swelling (IM use), fever. Other Serious Adverse Drug Reactions: allergic reactions (e.g. rash, urticaria, pruritus (uncommon in both adults and paediatric population), anaphylactic reactions and angioedema (frequency not known in both adults and paediatric population). *Prescribers should consult the SmPC in relation to other adverse reactions.*

**List price:** £72.29

**Legal Category:** POM

**Marketing Authorisation Number:** PLGB 23228/0001

**Marketing Authorisation Holder:** Sanofi Winthrop Industrie, 82 avenue Raspail, 94250 Gentilly, France.

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Adverse events should be reported. Reporting forms and information can be found at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

Adverse events should also be reported to the Sanofi drug safety department on Tel: 0800 0902 314. Alternatively, send via email to [UK-drugsafety@sanofi.com](mailto:UK-drugsafety@sanofi.com)