Prescribing Information: Verorab, powder and solvent for suspension for injection
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, WISTAR 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 is 0.5 mL of reconstituted vaccine intramuscularly (IM) (pre-exposure or post-exposure) or 0.1 mL of reconstituted vaccine intradermally (ID) (post-exposure only).
Dosage for Pre-exposure prophylaxis: The primary pre-exposure immunisation course consists of three doses of 0.5 mL of Verorab administered by intramuscular route at days (D) D0, D7 and D28. The dose scheduled at D28 can be administered at D21, if necessary. For individuals at continued risk, booster doses should be given in line with official recommendations. *Dosage for 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 subjects:* Post-exposure prophylaxis is recommended for both immunised and non-immunised subjects. Please see SmPC for recommended official guidelines.
Special Populations: *Paediatric population:* Children should receive the same dose as adults i.e. 0.5 mL intramuscularly (for pre-or post-exposure prophylaxis) or 0.1 mL intradermally (for post-exposure prophylaxis only). Please see SmPC for full dosage instructions.
Contraindications: *Pre-exposure prophylaxis:* Hypersensitivity to the active substance(s) or to any of the excipients listed in SmPC, to polymyxin B, to streptomycin, to neomycin or to any antibiotic of the same class 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.
Precautions and Warnings: *Special warnings:* As with all vaccines, Verorab may not protect 100% of vaccinated individuals. Use with caution in people with known allergies to polymyxin B, to streptomycin, to neomycin (present as traces in the vaccine) or to any antibiotic of the same class. *Precautions for use:* Injection-schedule recommendations should be followed scrupulously. The need for serological tests (to assess seroconversion in subjects) should be determined in accordance with official recommendations. When the vaccine is administered in subjects with known immunodeficiency, due to an immunosuppressive disease or a concomitant immunosuppressive treatment (including corticosteroids), blood tests must be performed 2 to 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). Do not inject via the intravascular route: make sure the needle does not penetrate a blood vessel. 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 subjects with a known hypersensitivity to polymyxin B, to streptomycin, to neomycin or to any antibiotic of the same class. As with all injectable vaccines, Verorab should be administered with caution in subjects with thrombocytopenia or coagulation disorders as intramuscular injection may induce bleeding in these subjects. 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. Verorab contains 4.1 micrograms phenylalanine per 0.5 mL dose which is equivalent to 0.068 microgram/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'. *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.
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 to 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.
Pregnancy: 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.

Lactation: 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.
Fertility: Verorab has not been evaluated in fertility studies.
Adverse Reactions: Very common (Adults): headache, myalgia, injection site pain (IM & ID use), injection site erythema (ID use), malaise. (Paediatric population): headache, irritability & somnolence (in infants/young children), myalgia, injection site pain (IM & ID use), injection site erythema (ID use), injection site swelling (ID use), malaise, inconsolable crying (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, decreased appetite, insomnia (in infants/young children), injection site erythema (IM use), injection site swelling (IM use), fever. Prescribers should consult the SmPC in relation to other adverse reactions.
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Legal Category: POM
Marketing Authorisation Number: PLGB 46602/0029
Marketing Authorisation Holder: Sanofi Pasteur, 14 Espace Henry Vallée, 69007 Lyon, France.
Further information is available from: Sanofi, 410 Thames Valley Park Drive, Reading, Berkshire, RG6 1PT. uk-medicalinformation@sanofi.com
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Adverse events should be reported. Reporting forms and information can be found at 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 UKdrugsafety@sanofi.com