Package leaflet: Information for the user

VERORAB®

Powder and solvent for suspension for injection
Rabies vaccine, inactivated

Read all of this leaflet carefully before you or your child are vaccinated because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicinal product has been prescribed for you only or has been prescribed to your child. Do not pass it on to others.
- If you or your child get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Verorab is and what it is used for
2. What you need to know before you use Verorab
3. How to use Verorab
4. Possible side effects
5. How to store Verorab
6. Contents of the pack and other information

1. What Verorab is and what it is used for

Verorab is a rabies vaccine indicated for pre-exposure and post-exposure rabies prophylaxis in all age groups.
Verorab should be used in accordance with official recommendations.

2. What you need to know before you use Verorab

Do not use Verorab

Pre-exposure prophylaxis:
- If you or your child are allergic to the active substance or any of the other ingredients of this medicine, listed in section 6.
- If you or your child developed an allergic reaction during a previous injection of this medicine or of any vaccine with the same composition.
- If you or your child are feverish or if you have an acute disease (in this case, it is preferable to postpone vaccination).

Post-exposure prophylaxis:
- Given the 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 people vaccinated.
- Verorab must not be administered via the intravascular route; make sure the needle does not penetrate a blood vessel.
- Use with caution if you or your child are allergic to polymyxin B, to streptomycin or to neomycin (present in trace amounts in the vaccine) or to any antibiotic of the same class.
- As with all injectable vaccines, appropriate medical treatment and supervision must be readily available in case of a rare anaphylactic reaction after vaccine administration.
- The need for serological tests (to assess seroconversion in the individuals) should be determined in accordance with official recommendations.
- When the vaccine is administered in individuals with a known reduction in immunity (immunodeficiency), due to an immunosuppressive disease or a concomitant immunosuppressive treatment, 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 in association with the vaccine in case of any category II or III exposure, see "**3. How to use Verorab**".
- Verorab should be administered with caution to individuals with a decreased platelet level (thrombocytopenia) or clotting disorders, because of the risk of bleeding that may occur during intramuscular administration.
- Tell your doctor, pharmacist or nurse before using Verorab, if you or your child have had any allergic reaction to latex. The tip cap of the prefilled syringe without attached needle contains a natural rubber latex derivative which may cause a severe allergic reaction.

Talk to your doctor, pharmacist or nurse before using Verorab.

Children and adolescents
Not applicable.

Other medicines and Verorab
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 get a serological test 2 to 4 weeks after vaccination; see "**Warnings and precautions**".
Verorab can be administered in association 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.
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.
Tell your doctor or pharmacist if you or your child are taking, has recently taken or might take any other medicines.

Verorab with food and drink
Not applicable.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.
Data on the use of Verorab in pregnant women are limited.
It is unknown whether Verorab is excreted in human milk, but no risk has been identified and is anticipated for infants receiving breast milk.
Given the seriousness of the disease, Verorab can be given during pregnancy or breast-feeding following an assessment of the risks and benefits by your physician.

Driving and using machines
Post-vaccination dizziness was frequently reported. This can temporarily affect the ability to drive or use machines.

Verorab contains phenylalanine, potassium and sodium
Verorab contains 4.1 micrograms phenylalanine in each 0.5 mL dose, which is equivalent to 0.068 microgram/kg for a 60 kg person. Phenylalanine may be harmful if you have 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'.

3. How to use Verorab

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
The recommended dose is 0.5 mL of reconstituted vaccine intramuscularly (IM) or 0.1 mL of reconstituted vaccine intradermally (ID) in each injection site.

- **Pre-exposure prophylaxis**

For primary pre-exposure immunisation, immunocompetent individuals can be vaccinated according to one of the vaccination schedules presented in Table 1 and according to local official recommendations when available:

Table 1: Pre-exposure vaccination schedules

	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 [a] IM route - 0.5 mL	1 dose	1 dose	-
Intradermal route (0.1 mL per dose)			
One-week regimen [a] ID route - 0.1 mL	2 doses [b]	2 doses [b]	-

a - This regimen should not be used for individuals with decreased immunity (see subsection "Individuals with decreased immunity")

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

Booster doses are determined based on the risk of exposure and on serological tests to detect the presence of rabies virus-neutralising antibodies (≥ 0.5 IU/ml). A booster dose consists of one dose of 0.5 mL given by intramuscular route or one dose of 0.1 mL given by intradermal route in accordance with WHO recommendations.

- **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 rabies vaccine or rabies immunoglobulin, where they are indicated.

Table 2: WHO Guide for post-exposure prophylaxis depending on level of exposure (adapt according to local official recommendations).

Exposure category	Type of exposure to a domestic or wild animal, suspected or confirmed to be rabid or not available for testing	Post-exposure prophylaxis recommended
I	Touching or feeding of animals Licks on intact skin (no exposure)	None if reliable case history is available.(a)
II	Nibbling of uncovered skin Minor scratches or abrasions without bleeding (exposure)	Administer the rabies vaccine immediately. Discontinue treatment if the animal is in good health after the 10-day observation period(b) or if the rabies test performed using appropriate laboratory methods is negative. Treat as category III if bat exposure involved.
III	Single or multiple transdermal bites(c) or scratches, licks on broken skin or contamination of mucous membrane with saliva (licks), exposure to bats (severe exposure)	Administer the rabies vaccine immediately. and rabies immunoglobulins, preferably as soon as possible after initiation of post-exposure prophylaxis. Rabies immunoglobulins can be injected up to 7 days after the first dose of vaccine is administered. Discontinue treatment if the animal is in good health after the 10-day observation period(b) or if the rabies test performed using appropriate laboratory methods is negative.

(a) If the animal is an apparently healthy dog or cat living in a low-risk area and placed under veterinary observation, treatment may be delayed.
(b) This observation period only applies to cats and dogs. With the exception of endangered or threatened species, domestic animals and wild animals suspected to have rabies should be euthanised and their tissues examined for the presence of rabies virus using appropriate laboratory methods.
(c) Bites, particularly to the head, neck, face, hands and genitals are classified as Category III exposure due to the extensive innervation of these parts of the body.

Post-exposure prophylaxis in non-immunised individuals
Non-immunised individuals may be vaccinated according to one of the vaccination regimens by intramuscular use (IM) or by intradermal use (ID) presented in table 3.

Table 3: Post-exposure prophylaxis of non-immunised individuals

	D0	D3	D7	D14	D21	D28
Intramuscular use (0.5 mL per dose)						
IM Essen protocol IM use – 0.5 mL/dose	1 dose	1 dose	1 dose	1 dose		1 dose
IM Zagreb protocol IM use – 0.5 mL/dose	2 doses(a)	-	1 dose	-	1 dose	-
Intradermal use (0.1 mL per dose)						
New Thailand Red Cross (TRC) ID regimen ID use – 0.1 mL/dose	2 doses(b)	2 doses(b)	2 doses(b)	-	-	2 doses(b)
Institute Pasteur of Cambodia (IPC) ID regimen ID use – 0.1 mL/dose	2 doses(b)	2 doses(b)	2 doses(b)	-	-	-
4-site 1-week ID regimen ID use – 0.1 mL/dose	4 doses(c)	4 doses(c)	4 doses(c)	-	-	-

(a) one IM injection in the anterolateral region of each thigh (in infants and young children) or in each deltoid (in older children and adults).
(b) to be injected in 2 separate sites, contralateral if possible.
(c) to be injected in 4 separate sites.

Irrespective of the regimen used, vaccination should not be discontinued unless the animal is declared free from rabies.

Rabies immunoglobulins should be administered in the event of any category III exposure (WHO classification, see Table 1). If possible, each dose of the vaccine should be administered at a body site distant from the immunoglobulin administration sites.

Post-exposure prophylaxis in already immunised individuals
In accordance with official recommendations, this applies to individuals who have already received pre-exposure prophylaxis or post-exposure prophylaxis or who discontinued post-exposure prophylaxis after receiving at least two doses of vaccine prepared in cell culture.
Individuals who have already been immunised must receive 1 dose of vaccine (0.5 mL intramuscularly or 0.1 mL intradermally) on D0 and 1 dose on D3. Alternatively, 4 intradermal injections of 0.1 mL may be administered in 4 separate sites on D0. Rabies immunoglobulins are not indicated in this case.

Individuals with decreased immunity

Pre-exposure prophylaxis
A 3-dose regimen should be used (listed in subsection "Pre-exposure prophylaxis") and a serological test for neutralising antibodies should be performed 2 to 4 weeks after the last dose to assess the possible need for an additional dose of vaccine.

Post-exposure prophylaxis
A complete vaccination regimen should be administered post-exposure. Rabies immunoglobulins should be administered in association with the vaccine in the event of any category II and III exposure (see Table 1).

Use in children
A child must receive the same dose as an adult.

Method of administration
- Intramuscular use (IM)
  The vaccine is administered in the anterolateral region of the thigh muscle in infants and young children and in the deltoid muscle in older children and adults.
  If the Zagreb regimen is used, one dose should be administered in each deltoid muscle (left and right) in adults at D0, then one dose at D7 and D21.
- Intradermal use (ID)
  The vaccine is administered preferably in the upper arm or the forearm.
  Verorab must not be injected in the buttock region.
  The vaccine must not be injected via the intravascular route.

If you or your child use more Verorab than you should
Not applicable.

If you or your child forget to use Verorab
Not applicable.

If you or your child stop using Verorab
Not applicable.
If you have any further questions on the use of this medicine, ask your doctor or pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious allergic reactions:
Serious allergic reactions (anaphylactic reactions) can always happen, even if it is very rare. Contact your doctor or health care professional immediately or go to the nearest hospital emergency department immediately if you or your child experience an anaphylactic reaction.
Signs or symptoms of an anaphylactic reaction usually occur very soon after the injection if at all, and may include rash, itching, difficulty breathing, shortness of breath and swelling of the face, lips, throat or tongue.

Other side effects
Most side effects occur within 3 days of vaccination. The effects most often resolve spontaneously within 1 to 3 days of onset. They have been reported with the following frequencies:

Very common: may affect more than 1 in 10 people
- Generally feeling unwell,
- Headache (cephalalgia),
- Muscle pain (myalgia),
- Pain at the injection site,
- Redness (erythema) at the injection site,
- Swelling at the injection site,
- Only in babies: irritability, inconsolable crying and drowsiness.

Common: may affect up to 1 in 10 people
- Fever,
- Increase in size of lymph nodes (lymphadenopathy),
- Allergic reactions, such as rash and itching,
- Flu-like syndrome,
- Itching (pruritus) at the injection site,
- Induration at the injection site,
- Only in babies: difficulty sleeping.

Uncommon: may affect up to 1 in 100 people
- Decreased appetite,
- Nausea,
- Stomach pain (abdominal pain),
- Diarrhoea,
- Vomiting,
- Chills,
- Fatigue, unusual weakness (asthenia),
- Dizziness,
- Joint pain (arthralgia),
- Bruising at the injection site (ecchymosis).

Rare: may affect up to 1 in 1000 people
- Difficulty breathing.

Not known: cannot be estimated from the available data
- Swelling of the face, lips, mouth, tongue or throat, which may cause difficulty swallowing or breathing,
- Sudden hearing loss/decrease.

Reporting of side effects
If you or your child get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Medicines and Healthcare products Regulatory Agency (MHRA), Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Verorab

Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date which is stated on the box after EXP. The expiry date refers to the last day of that month.
Store in a refrigerator (2°C – 8°C). Do not freeze.
Store in the original outer package, protected from light.
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Verorab contains
- The active substance is:

After reconstitution with 0.5 mL solvent, 1 vial contains:
Rabies virus[a], WISTAR Rabies PM/WI38 1503-3M strain (inactivated) . . . . . 3.25 IU[b]

[a] Produced in Vero cells
[b] Quantity measured according to the ELISA test against the international standard

- The other ingredients are:

Powder: maltose, 20% human albumin solution, Basal Medium Eagle (mixture of mineral salts including potassium, vitamins, dextrose and amino acids including L-phenylalanine), water for injections, hydrochloric acid and sodium hydroxide.
Solvent: sodium chloride, water for injections.
May contain traces of polymyxin B, streptomycin and neomycin, used in the manufacturing process; see "Warnings and precautions".

What Verorab looks like and contents of the pack
Verorab is a powder and a solvent for suspension for injection (powder in vial + 0.5 mL of solvent in prefilled syringe with or without needle – Box of 1 or 10).

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder:
Sanofi Pasteur - 14 Espace Henry Vallée - 69007 Lyon – France
Distributed by:
Sanofi - 410 Thames Valley Park Drive – Reading – Berkshire - RG6 1PT - UK
Tel: 0800 035 2525

Manufacturer:
Sanofi Pasteur - 1541 avenue Marcel Mérieux - 69280 Marcy l'Etoile - France
Sanofi Pasteur - Parc Industriel d'Incarville - 27100 Val de Reuil - France
Sanofi-Aventis Zrt. Bdg. DC5 - Campona Utca 1. Budapest XXII - 1225 Budapest – Hungary

This leaflet was last revised in December 2023.

The following information is intended for healthcare professionals only:
Injection-schedule recommendations should be followed scrupulously.
Handling instructions:
- Remove the cap of the vial of lyophilised powder.
- Screw the plunger rod into the syringe, if provided separately.
- For syringe without needle: Attach the reconstitution needle to the syringe
- Inject 0.5 mL of solvent into the vial of lyophilised powder.
- Shake the vial gently until homogeneous suspension of the powder is obtained.
- The reconstituted vaccine should be limpid, homogeneous and free from particles.
  - o For syringe with attached needle
    - ▪ Remove and discard the syringe that was used for vaccine reconstitution.
    - ▪ Use a new syringe with a new needle to withdraw the reconstituted vaccine.
  - o For syringe without needle
    - ▪ Withdraw the suspension using a syringe.
- Replace the needle used to withdraw the vaccine with a new needle for intramuscular or intradermal injection.
- The length of the needle used for vaccine administration should be adapted to the patient.

If Verorab is administered **intramuscularly**, the vaccine must be used immediately after reconstitution.
If Verorab is administered **intradermally**, the vaccine may be used up to 6 hours after reconstitution on the condition that is stored at a temperature below 25°C and protected from light. After reconstitution with 0.5 mL of solvent, using aseptic techniques, each doseof 0.1 mL must be taken from the vial. The rest may be used for another patient. Before each withdrawal, shake the vial gently to obtain a homogenous suspension. A new sterile needle and a new sterile syringe must be used to withdraw and administer each vaccine dose to each patient to avoid cross-infection. The unused reconstituted vaccine must be thrown away after 6 hours.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.
This medicinal product is subject to medical prescription.

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