Verorab[®]

Consumer Medicine Information (CMI) summary

The <u>full CMI</u> on the next page has more details. If you are worried about you or your child receiving this medicine, speak to your doctor or pharmacist.



This medicine is new or being used differently. Please report side effects. See the full CMI for further details.

1. Why am I or my child receiving Verorab?

Verorab contains the active ingredient rabies virus (inactivated). Verorab is a vaccine used to help prevent rabies infection in people who have been, or are likely to be, bitten, licked, or scratched by an animal that has or is suspected to have rabies. For more information, see Section 1. Why am I or my child receiving Verorab? in the full CMI.

2. What should I know before I or my child receives Verorab?

Do not use if you or your child has ever had an allergic reaction to Verorab or any of the ingredients listed at the end of the CMI, UNLESS bitten, licked, or scratched by an animal that is suspected to have rabies. Do not use if you or your child has a high temperature or serious illness, UNLESS bitten, licked, or scratched by an animal that is suspected to have rabies.

Talk to your doctor if you or your child has any other medical conditions or is taking any other medicines. Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I or my child receives Verorab? In the full CMI.

3. What if I or my child is taking other medicines?

Some medicines may interfere with Verorab and affect how it works.

A list of these medicines is in Section 3. What if I or my child is taking other medicines? In the full CMI.

4. How do I or my child receive Verorab?

Verorab is given as an injection, usually into muscle in the upper arm or in the skin, by a doctor or nurse. Your doctor will decide how many injections you or your child should have and when they should have them. Carefully follow all of your doctor's directions.

More instructions can be found in Section 4. How do I or my child receive Verorab? In the full CMI.

5. What should I know after I or my child receives Verorab?

Things you should do	 Keep an updated record of you or your child's vaccinations. Keep follow-up appointments with your doctor or clinic. It is important to have follow-up doses of Verorab, and any blood tests, at the correct intervals. 	
Looking after your medicine	Verorab is usually stored in the doctor's surgery or clinic. However, if you need to store Verorab: Keep it where children cannot reach it. Keep it in the original pack. Keep it in the refrigerator, between 2°C and 8°C. Do not freeze it.	

For more information, see Section 5. What should I know after I or my child receives Verorab? In the full CMI.

6. Are there any side effects?

Very common side effects include feeling unwell, headache, sore muscles, pain, redness or swelling at the injection site, and in babies, irritability, inconsolable crying and drowsiness. These side effects are mild and short-lived.

Serious side effects include serious allergic reactions. Symptoms include itchy swellings, swelling of the face, lips, tongue, or other parts of the body, and rash.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? In the full CMI.

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This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

Verorab[®]

Active ingredient: Rabies virus (inactivated)

Consumer Medicine Information (CMI)

This leaflet provides important information about Verorab. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about you or your child receiving Verorab.

Where to find information in this leaflet:

- 1. Why am I or my child receiving Verorab?
- 2. What should I know before I or my child receives Verorab?
- 3. What if I or my child is taking other medicines?
- 4. How do I or my child receive Verorab?
- 5. What should I know after I or my child receives Verorab?
- 6. Are there any side effects?
- 7. Product details

1. Why am I or my child receiving Verorab?

Verorab contains the active ingredient, rabies virus (inactivated). Verorab is a vaccine used to help prevent rabies infection in people who have been, or are likely to be, bitten, licked, or scratched by an animal that has rabies. Verorab works by causing your body to produce antibodies against rabies virus.

Verorab is used to help prevent rabies infection. However, as with all vaccines, 100% protection cannot be guaranteed.

2. What should I know before I or my child receives Verorab?

Warnings

Do not receive Verorab if:

- you or your child is allergic to Verorab, or any of the ingredients listed at the end of this leaflet UNLESS bitten, licked, or scratched by an animal that is suspected to have rabies.
- you or your child has a high temperature or serious illness UNLESS bitten, licked, or scratched by an animal that is suspected to have rabies.

Always check the ingredients to make sure you or your child can receive this vaccine.

Check with your doctor if you or your child:

 has any other medical conditions such as low immunity due to an illness or treatment with medicines such as corticosteroids, ciclosporin or cancer treatment (including radiation therapy).

- experience anxiety problems, such as breathing fast, fainting, unusual skin sensations, before or after receiving needle injections.
- ever had an allergic reaction to antibiotics
- take any medicines for any other condition, for example antibiotics.

During treatment, you or your child may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section <u>6</u>. Are there any side <u>effects?</u>

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

3. What if I or my child is taking other medicines?

Tell your doctor or pharmacist if you or your child is taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Verorab and affect how it works.

- medicines which lower the immune system, such as corticosteroids, ciclosporin or other medicines used to treat cancer (including radiation therapy).
- antirabies immunoglobulin (used to treat confirmed rabies infection).

Verorab can be administered at the same time as a typhoid fever vaccine in 2 separate injection sites.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you or your child is taking and if these affect Verorab.

4. How do I or my child receive Verorab?

How much to receive

- Verorab is given as an injection, usually into muscle in the upper arm or in the skin.
- Your doctor will decide how many Verorab injections are needed.

When to receive Verorab

 Verorab may be given to people who are at risk of infection with rabies virus because of specific occupation (e.g., vets) or travel to areas where rabies is common. Verorab is also given to people after being bitten, licked, or scratched by an animal that is suspected to have rabies.

 Your doctor will tell you how many injections you or your child should have and when they should have them. Carefully follow all of your doctor's directions.

If you forget to receive Verorab

If you or your child miss a dose, talk to your doctor and arrange another visit as soon as possible.

If you or your child receive too much Verorab

Overdose is most unlikely because your doctor or nurse gives the injections. If you have any concerns, ask your doctor.

5. What should I know after I or my child receives Verorab?

Things you should do

- Keep an updated record of you or your child's vaccinations.
- Keep follow-up appointments with your doctor or clinic. It is important to have follow-up doses of Verorab, and any blood tests, at the correct intervals. This gives the vaccine the best chance of providing protection against rabies.

Tell any doctor, dentist or pharmacist you visit that you or your child have received Verorab.

Looking after your medicine

Verorab is usually stored in the doctor's surgery or clinic, or at the pharmacy. However, if you need to store Verorab:

- Keep it where children cannot reach it.
- Keep it in the original pack.
- Keep it in the refrigerator, between 2°C and 8°C. Do not freeze it. Freezing destroys the vaccine.

Getting rid of any unwanted medicine

If you no longer need to use this vaccine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this vaccine after the expiry date.

6. Are there any side effects?

All vaccines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects		What to do
•	pain, redness, swelling, bruising or itching where the injection	Speak to your doctor if you or
	was given	your child have

Less serious side effects	What to do
 headache dizziness or light-headedness muscle ache, tenderness or weakness painful or swollen joints "pins and needles", tingling sensation nausea, vomiting or diarrhoea stomach cramps or pain bodily discomfort, feeling unwell flu-like symptoms tiredness, lack of energy chills fever swollen glands breathing difficulties inconsolable crying (in infants/toddlers only) inability to sleep (in 	any of these less serious side effects and they worry you.
 painful or swollen joints "pins and needles", tingling sensation nausea, vomiting or diarrhoea stomach cramps or pain bodily discomfort, feeling unwell flu-like symptoms tiredness, lack of energy chills fever swollen glands breathing difficulties inconsolable crying (in infants/toddlers only) 	1

Serious side effects

Serious side effects	What to do
 Signs of allergy such as, itching or pinkish, itchy swellings on the skin (also called hives or nettle rash), swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing, rash. 	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you or your child feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you or your child experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems (Australia) or to Medsafe at

https://pophealth.my.site.com/carmreportnz/s/ (New Zealand). By reporting side effects, you can help provide more information on the safety of this vaccine.

Always make sure you speak to your doctor or pharmacist before you decide to stop receiving any of your medicines.

7. Product details

This vaccine is only available with a prescription.

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What Verorab contains

Each pack of Verorab contains one vial of vaccine powder and one prefilled syringe.

Vial of Vaccine Powder

Active ingredient (main ingredient)	3.25 International Units of rabies virus (inactivated) (WISTAR Rabies PM/WI 38 1503-3M strain)
Other ingredients (inactive ingredients)	Maltose 20% albumin solution Basal Medium Eagle: mixture of mineral salts, vitamins, dextrose and amino-acids including L-Phenylalanine Water for injections Hydrochloric acid and sodium hydroxide
Potential allergens	Neomycin, streptomycin and polymyxin
Excipient with known effect	Phenylalanine (4.1 micrograms)

Prefilled syringe

Ingredient	Sodium chloride 0.4%
	Water for injections

Do not receive this vaccine if you or your child is allergic to any of these ingredients, UNLESS bitten, licked, or scratched by an animal that is suspected to have rabies.

What Verorab looks like

Your doctor or nurse will prepare the vaccine by mixing the vial of vaccine powder with the solution in prefilled syringe. The liquid is clear and colourless.

AUST R 371727.

Who distributes Verorab?

Distributed in Australia by: sanofi-aventis australia pty ltd 12-24 Talavera Road

Macquarie Park NSW 2113

Freecall: 1800 818 806

Email: medinfo.australia@sanofi.com

Distributed in New Zealand by:

Pharmacy Retailing (NZ) Ltd t/a Healthcare Logistics

PO Box 62027

Sylvia Park Auckland 1644 Freecall: 0800 283 684

Email: medinfo.australia@sanofi.com

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