Consumer Medicine Information (CMI) summary

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

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.

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. Do not use if you or your child has a high temperature or serious illness.

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 <u>3. What if I or my child is taking other medicines?</u> 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, or at the pharmacy. However, if you need to store Verorab: Keep it where children cannot reach it. Keep it in the original pack until it is time for it to be given. 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, rash, itchy swellings, swelling of the face, lips, tongue, or other parts of the body.

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

Verorab[®]

Active ingredient(s): 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 protect itself against rabies.

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 they have been bitten or scratched by an animal that has rabies.
- you or your child has a high temperature or serious illness.

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 or latex
- 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. Are there any side 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 injections 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, by a doctor or nurse. Your doctor will decide how much Verorab is needed.

When to receive Verorab

- Verorab may be given in advance to people at risk of getting rabies. Verorab is also given to people after they have been exposed to rabies infection.
- The usual course is 3 to 5 injections, given at intervals over 1 to 4 weeks.

- After one year, depending on the circumstances, a booster injection may be needed. Further boosters may be needed every few years.
- 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 and allows the antibody level to be measured.
- Remind 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 until it is time for it to be given.
- 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 or your child 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
The following side effects are mild and short-lived.		Speak to your doctor if you or your child have any of these less
•	any effects at	serious side effects and they
	the injection	worry you.
	site, such as	
	pain, redness,	
	swelling,	
	hardness,	
	bruising or	
	itching	
•	headache	
•	dizziness or	
	light-	
	headedness	
•	muscle ache,	
	tenderness or	
	weakness	
•	painful or	
	swollen joints	
•	nausea,	
	vomiting or	
	diarrhea	
•	stomach	
	cramps or pain bodily	
•	discomfort,	
	feeling unwell	
•	flu-like	
	symptoms	
•	tiredness, lack	
	of energy	
•	chills	
•	fever	
•	swollen glands	
•	breathing	
	difficulties	
•	irritability,	
	inconsolable	
	crying and	
	drowsiness (in	
	infants/toddlers	
	only)	
•	inability to	
	sleep (in infants/toddlers	
	-	
	only) sudden hearing	
1	loss	
	1022	

Serious side effects

Serious side effects	What to do
 signs of allergy such as, rash, 	Call your doctor straight away or go straight to the Emergency Department at your nearest

•	itching or	hospital if you notice any of
	pinkish,	these serious side effects.
	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.	

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 <u>www.tga.gov.au/reporting-problems</u> (Australia) or <u>https://nzphvc.otago.ac.nz/reporting/</u> (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 doctor's prescription.

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% Human 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.
Excipient with known effect	Phenylalanine (4.1 micrograms)
Potential allergens	Neomycin, streptomycin and polymyxin

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.

What Verorab looks like

Your doctor will inject the sterile diluent into the vial to make the liquid for injection. This liquid is a 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 Australia Freecall : 1800 818 806 Email: <u>medinfo.australia@sanofi.com</u>

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: <u>medinfo.australia@sanofi.com</u>

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