

Merieux Inactivated Rabies Vaccine (MIRV)

Consumer Medicine Information (CMI) summary

The [full CMI](#) 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 MIRV?

MIRV contains the active ingredient rabies virus (inactivated). MIRV 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 MIRV?](#) in the full CMI.

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

- Do not use if you or your child has ever had an allergic reaction to MIRV 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 me or my child receives MIRV?](#) in the full CMI.

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

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

A list of these medicines is in Section [3. What if me or my child is taking other medicines?](#) in the full CMI.

4. How do I or my child receive MIRV?

- MIRV is given as an injection, usually into muscle in the upper arm, by a doctor or nurse. Your doctor will decide how much MIRV is needed.
- 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.

More instructions can be found in Section [4. How do I or my child receive MIRV?](#) in the full CMI.

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

Things you should do	<ul style="list-style-type: none">• 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 MIRV, and any blood tests, at the correct intervals.• Remind any doctor, dentist or pharmacist you visit that you or your child has received MIRV.
Looking after your medicine	MIRV is usually stored in the doctor's surgery or clinic, or at the pharmacy. However, if you need to store MIRV: <ul style="list-style-type: none">• 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 me or my child receives MIRV?](#) in the full CMI.

6. Are there any side effects?

Common side effects include, local reactions at the injection site, headache, nausea, sore, tender, or weak muscles, fever, feeling tired or lack of energy. 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 [6. Are there any side effects?](#) in the full CMI.

Merieux Inactivated Rabies Vaccine (MIRV)

Active ingredient(s): *Rabies virus (inactivated)*

Consumer Medicine Information (CMI)

This leaflet provides important information about MIRV.

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 MIRV.

Where to find information in this leaflet:

- [1. Why am I or my child receiving MIRV?](#)
- [7. What should I know before me or my child receives MIRV?](#)
- [8. What if me or my child is taking other medicines?](#)
- [9. How do I or my child receive MIRV?](#)
- [10. What should I know after me or my child receives MIRV?](#)
- [11. Are there any side effects?](#)
- [12. Product details](#)

1. Why am I or my child receiving MIRV?

MIRV contains the active ingredient, rabies virus (inactivated). MIRV 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. MIRV works by causing your body to protect itself against rabies.

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

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

Warnings

Do not receive MIRV if:

- you or your child is allergic to MIRV, 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
 - low immunity due to an illness or treatment with medicines such as corticosteroids, ciclosporin or cancer treatment (including radiation therapy).
 - bleeding problems or bruise easily.
 - experience anxiety problems, such as breathing fast, fainting, unusual skin sensations, before or after receiving needle injections.
 - take any medicines for any other condition

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 [6. Are there any side effects?](#)

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 me 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 MIRV 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).

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 MIRV.

4. How do I or my child receive MIRV?

How much to receive

- MIRV is given as an injection, usually into muscle in the upper arm, by a doctor or nurse. Your doctor will decide how much MIRV is needed.

When to receive MIRV

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

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 MIRV

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 me or my child receives MIRV?

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 MIRV, 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 MIRV.

Looking after your medicine

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

- 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
<p>The following side effects are mild and short-lived.</p> <ul style="list-style-type: none"> • any effects at the injection site, such as pain, redness, swelling, bruising or itching. • headache • dizziness or light-headedness • muscle ache, tenderness or weakness • painful or swollen joints • "pins and needles", tingling sensation • nausea, vomiting or diarrhea • stomach cramps or pain • bodily discomfort, feeling unwell • tiredness, lack of energy • chills • fever • swollen glands 	<p>Speak to your doctor if you or your child have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>The following side effects are rare.</p> <ul style="list-style-type: none"> • signs of allergy such as, <ul style="list-style-type: none"> ○ rash, ○ 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. • a hypersensitivity reaction associated with the presence of betapropiolactone-altered human albumin in the vaccine. <ul style="list-style-type: none"> ○ symptoms include fever, swelling, skin rash, enlargement of the lymph nodes • numbness or weakness of the arms and legs • convulsions • swelling or infection of the brain <ul style="list-style-type: none"> ○ symptoms include headache and fever, progressing to hallucinations, confusion, paralysis of part or all of the body, disturbances of behaviour, speech and eye movements, stiff neck and sensitivity to light • 	<p>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.</p>

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. 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 MIRV contains

Each pack of MIRV contains one vial of vaccine powder and one prefilled syringe, which contains sterile water.

Vial of Vaccine Powder

Active ingredient (main ingredient)	Not less than 2.5 International Units of rabies virus (inactivated) (WISTAR Rabies PM/WI 38 1503-3M strain).
Other ingredients (inactive ingredients)	100-150 micrograms of Neomycin (antibiotic) up to 70 mg of albumin
Potential allergens	Neomycin

Prefilled syringe

Ingredient	1 mL of water for injections
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Do not receive this vaccine if you or your child is allergic to any of these ingredients.

The manufacture of this product includes exposure to bovine materials. No evidence exists that any case of vCJD (considered to be the human form of bovine spongiform encephalopathy) has resulted from the administration of any vaccine product.

What MIRV looks like

Your doctor will inject the sterile water into the vial to make the liquid for injection. This liquid is a red to purple-red colour.

AUST R 26675

Who distributes MIRV?

Australia:

sanofi-aventis australia Pty Ltd

12 - 24 Talavera Road

Macquarie Park NSW 2113 Australia

Tel: 1800 818 806

New Zealand:

sanofi-aventis new zealand limited

Level 8

56 Cawley St

Ellerslie

Auckland

New Zealand

Tel: 0800 283 684

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