

MERIEUX INACTIVATED RABIES VACCINE (MIRV)

Rabies Vaccine

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about **Merieux Inactivated Rabies Vaccine (MIRV)**.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines, including vaccines, have risks and benefits. Your doctor has weighed the risks of you or your child having MIRV against the benefits they expect it will have.

If you have any concerns about this vaccine, ask your doctor, nurse or pharmacist.

Keep this leaflet.

You may need to read it again.

What MIRV is used for

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.

Rabies is a serious infection caused by a virus. The virus affects the brain. Rabies is fatal if not treated early.

How it works

MIRV works by causing your body to protect itself against rabies. The body makes substances which fight the rabies virus. They are called antibodies and circulate in the blood. If the rabies virus gets into a vaccinated person, the antibodies destroy the virus before it can cause damage. After vaccination

your body takes several weeks to develop adequate antibodies against rabies.

For vaccination against rabies you need a course of 3 injections. After 1 year another (booster) injection may also be required. Further booster injections may be needed every few years.

After this course, most people produce enough antibodies against rabies. However, as with all vaccines, 100% protection cannot be guaranteed.

The vaccine will not give you or your child rabies.

The chance of a severe reaction from MIRV is very small, but the risks from not being vaccinated against rabies may be very serious.

Before you are given MIRV

When you or your child must not be given it

Do not have MIRV if you have an allergy to:

- MIRV or any of the ingredients listed at the end of this leaflet **UNLESS** you have been bitten or scratched by an animal that has rabies.

Do not have MIRV after the expiry date printed on the pack.

Do not have MIRV if the packaging is torn or shows signs of tampering.

If you are not sure whether you or your child should have MIRV,

talk to your doctor or pharmacist.

Before you or your child is given it

Tell your doctor if you have, or have had, any medical conditions, especially the following:

- Low immunity due to an illness OR treatment with medicines such as corticosteroids, cyclosporin or cancer treatment (including radiation therapy).

Tell your doctor if you are pregnant or intend to become pregnant.

Your doctor will discuss the possible risks and benefits of having MIRV during pregnancy.

Tell your doctor if you are breast-feeding.

Your doctor will discuss the possible risks and benefits of having MIRV during breastfeeding.

Taking other medicines

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

MIRV and some medicines may interfere with each other. These include:

- medicines which lower the immune system, such as corticosteroids, cyclosporin or other medicines used to treat cancer (including radiation therapy)

- antirabies immunoglobulin (used to treat confirmed rabies infection)

These medicines may be affected by MIRV, or may affect how well it works. (You may need different amounts of these medicines, or you may need to take different medicines.) Your doctor or pharmacist will advise you.

How MIRV is given

MIRV is given as an injection, (usually into muscle in your upper arm) by a doctor or nurse.

MIRV should not be injected directly into the skin or a vein.

How much is given

Your doctor will decide how much MIRV you need.

When it is given

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 should have and when you should have them.

Follow carefully all your doctor's directions.

If you miss a dose

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

Overdose

Overdose is most unlikely because your doctor or nurse gives the injections.

If you have any concerns, ask your doctor.

After having MIRV

Things you or your child must do

Keep an updated record of your vaccinations.

Keep follow-up appointments with your doctor or clinic.

It is important to have your 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.

Side effects

Tell your doctor or pharmacist as soon as possible if you or your child does not feel well after having MIRV.

Ask your doctor or pharmacist to answer any questions you may have.

MIRV may have unwanted side effects in a few people. All medicines, including vaccines, have side effects. Sometimes they are serious, most of the time they are not. You or your child may need medical treatment if you get some of the side effects.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- any effects at the injection site
- headache
- dizziness or light-headedness
- mild flu-like symptoms, such as high temperature or chills
- muscle ache, tenderness or weakness
- nausea or vomiting
- stomach cramps or pain

These are common side effects of MIRV. Mostly these are mild and short-lived.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- signs of allergy such as rash, itching or pinkish, itchy swellings

on the skin (also called hives or nettle rash), swelling of the face, lips, tongue or other parts of the body.

These are very serious side effects. You or your child may need urgent medical attention or hospitalisation.

All of these side effects are rare.

This is not a complete list of side effects. Tell your doctor or pharmacist if you notice anything related to MIRV that makes you or your child feel unwell.

Storing MIRV

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 MIRV 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 MIRV.** Freezing destroys the vaccine.

Product description

What MIRV looks like

Each pack of MIRV contains one vial of vaccine powder and one prefilled syringe, which contains sterile water. Your doctor will inject the sterile water into the vial to make the liquid for your injection. This liquid is a red to purple-red colour.

Ingredients

Vaccine

Active ingredients:

- Not less than 2.5 International Units of inactivated Rabies virus (WISTAR Rabies PM/WI 38 1503-3M strain).

Other ingredients

- 100-150 micrograms of neomycin (antibiotic)
- up to 70 mg of human serum albumin

The rabies virus that this vaccine contains was grown in a cell line derived from human embryonic lung in the 1960s.

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.

Diluent

- Water for injections

MIRV does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Manufacturer

Sanofi Pasteur SA
Lyon, France

Distributor

Australia:

Sanofi Pasteur Pty Ltd
ABN 79 085 258 797
Talavera Corporate Centre –
Building D
12 – 24 Talavera Road
Macquarie Park NSW 2113
Australia
Tel: 1800 829 468

New Zealand:

**sanofi-aventis new zealand
limited**
Level 8, James & Wells Tower
56 Cawley St
Ellerslie
Auckland
New Zealand
Tel: 0800 727 838

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