

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

IMOVAX® Rabies

Inactivated Rabies Virus (PM/WI38 1503-3M)

Read this carefully before you or your child start taking IMOVAX® Rabies. This leaflet is a summary and will not tell you everything about this vaccine. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about taking IMOVAX® Rabies.

What is IMOVAX® Rabies used for?

- IMOVAX® Rabies is a vaccine used to prevent rabies. IMOVAX® Rabies is given to persons at high risk of exposure to rabies as a result of their employment, travel, hobbies, etc. It can also prevent the disease if it is given to a person after they have been exposed to rabies following an animal bite or other similar incident. This vaccine may be given to adults and children of any age.
- **Vaccination After an Exposure:**

Anyone who has been bitten, scratched or licked on an open wound or sore by an animal suspected of having rabies should get this vaccine. In all cases, proper wound care (thorough flushing and washing of the wound with soap or detergent and water and/or virucidal agents) must be performed as soon as possible after exposure. It must be performed before administration of rabies vaccine or rabies immunoglobulin where they are indicated. The rabies vaccine administration must be carried out by appropriately trained medical staff and should be given as soon as possible to everyone who has had contact with the animal.

In addition, tetanus prophylaxis and a course of antibiotics to prevent superinfections should be given as required.
- **Preventive Vaccination (No Exposure):**

Rabies vaccine is indicated for pre-exposure prophylaxis of persons who are at high risk of contact with potentially rabid animals or the rabies virus. This includes, for example, certain laboratory workers, veterinarians, animal handlers potentially exposed to rabid animals, spelunkers (cave explorers), hunters and trappers in high-risk areas and international travellers including children, who are likely to come in contact with animals in parts of the world where rabies is common or those intending to live or work in such areas.

How does IMOVAX® Rabies work?

IMOVAX® Rabies causes your body to produce its own protection against the rabies virus. When you get a series of rabies vaccine injections, your immune system produces antibodies against the virus in the vaccine. When you are in contact with the rabies virus, the antibodies will prevent rabies disease.

A series of shots is needed to protect you or your child against rabies.

What are the ingredients in IMOVAX® Rabies?

Medicinal ingredients: Inactivated Rabies Virus (PM/WI38 1503-3M)

Non-medicinal ingredients: human albumin, neomycin, phenol red indicator, sterile water

IMOVAX® Rabies comes in the following dosage forms:

IMOVAX® Rabies is supplied as a freeze-dried powder in a vial with a disposable syringe containing 1 mL of diluent (sterile water for injection). After mixing the powder and diluent, IMOVAX® Rabies is a suspension with strength ≥ 2.5 IU/mL.

Do not use IMOVAX® Rabies if:

- You have a known severe allergy to any ingredient in IMOVAX® Rabies or its container.
- You have a high fever or serious illness. Delay the vaccination until you feel better.

Everyone should get the vaccine if there is a risk of getting rabies following contact with an animal.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Imovax® Rabies. Talk about any health conditions or problems you may have, including if you:

- **Have any allergies to this vaccine or its ingredients or components of the container.**
- **Have a bleeding disorder or are taking blood thinning medications.** Tell the person giving you the injection about your condition. The injection must be done carefully to prevent excessive bleeding.
- **Have a weakened immune system because of HIV/AIDS, cancer, or another disease that affects the immune system; treatment with drugs that affect the immune system such as steroids; cancer treatment with drugs or radiation.** The vaccine may provide you with a lower level of protection than it does for people with healthy immune systems.
- **Are pregnant or breast-feeding.** It is important that you understand the risks and benefits of vaccination. Tell the person giving you the injection if you are pregnant or breast-feeding.

If you have been exposed to rabies virus, you should get the vaccine regardless of any other illnesses you may have.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with IMOVAX® Rabies:

- Any drugs or treatments which may weaken the immune system.

DO NOT mix IMOVAX® Rabies with other vaccines or medicinal products in the same syringe.

DO NOT give IMOVAX® Rabies at the same injection site as Rabies Immunoglobulin.

How to take IMOVAX® Rabies:

Usual dose:

One dose of IMOVAX® Rabies is an injection of 1.0 mL.

Vaccination After an Exposure:

A person who is exposed and has never been vaccinated against rabies should get 5 doses of rabies vaccine - one dose right away, and additional doses on the 3rd, 7th, 14th, and 28th days. He or she should also get injection(s) of Rabies Immunoglobulin at the same time as the first dose. This gives immediate protection.

A person who has been previously vaccinated should get 2 doses of rabies vaccine - one right away and another on the 3rd day. Rabies Immunoglobulin is not needed.

Pre-exposure:

The pre-exposure schedule for rabies vaccination is 3 doses, given at the following times:

Dose 1: As appropriate

Dose 2: 7 days after Dose 1

Dose 3: 21 days after Dose 1

For laboratory workers, veterinarians and others who may be repeatedly exposed to rabies virus, periodic testing for immunity is recommended, and booster doses should be given as needed. Ask your doctor for details.

Rabies vaccine must be injected into the deltoid muscle (or into the thigh muscle in children under one year of age). There have been reports of vaccine failure (rabies) when the vaccine was injected into the buttocks.

Overdose:

If you think you, or a person you are caring for, have taken too much Imovax® Rabies, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

It is very important to complete the series of rabies vaccinations on time. Cases of rabies have been reported when the approved vaccination schedule was not followed. If you miss a dose, contact your doctor to schedule a visit.

What are possible side effects from using IMOVAX® Rabies?

These are not all the possible side effects you may have when taking IMOVAX® Rabies. If you experience any side effects not listed here, tell your healthcare professional.

A vaccine, like any medicine, may cause serious problems, such as severe allergic reactions. The risk of IMOVAX® Rabies causing serious harm is extremely small. The small risks associated with IMOVAX® Rabies are much less than the risks associated with getting rabies.

Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well after receiving IMOVAX® Rabies.

Rabies vaccine cannot cause rabies because it does not contain any live virus.

Some people who receive IMOVAX® Rabies may have side effects such as swollen lymph nodes, hives, rash, shortness of breath, wheezing, headache, dizziness, nausea, abdominal pain, vomiting, diarrhea, muscle aches, pain in joints, bodily discomfort, fever or chills. Some people who receive IMOVAX® Rabies may have pain, redness, swelling, bruising or itching at the site where the needle was given.

Fainting can occur following, or even before, any needle injection. Therefore, tell your healthcare professional if you have fainted with a previous injection.

Nervous system disorders have been reported after rabies vaccine, but this happens so rarely that it is not known if they are related to the vaccine.

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Suspected Side Effects for Vaccines

For the general public: Should you experience a side effect following immunization, please report it to your healthcare professional.

Should you require information related to the management of the side effect, please contact your healthcare professional. The Public Health Agency of Canada, Health Canada and Sanofi Pasteur cannot provide medical advice.

For healthcare professionals: If a patient experiences a side effect following immunization, please complete the Adverse Events Following Immunization (AEFI) Form appropriate for your province/territory (<http://www.phac-aspc.gc.ca/im/ae-fi-essi-form-eng.php>) and send it to your local Health Unit.

Storage:

Store in a refrigerator at 2° to 8°C (35° to 46°F). DO NOT FREEZE. Discard product if it has been exposed to freezing.

Do not use vaccine after expiration date.

The vaccine must be used immediately after mixing.

Keep out of reach and sight of children.

If you want more information about Imovax® Rabies:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>; the Sanofi Canada website (www.sanofi.com/en/) or by calling the vaccine producer, Sanofi Pasteur Limited at 1-888-621-1146 (no charge).

This leaflet was prepared by Sanofi Pasteur Limited.

Last Revised: JULY 02, 2024

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