

PACKAGE LEAFLET: INFORMATION FOR THE USER

Rabies Vaccine BP \geq 2.5 IU/ml Powder and solvent for suspension for injection

Read all of this leaflet carefully before you or your child are vaccinated.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, nurse or pharmacist.
- This vaccine has been prescribed for you. Do not pass it on to others.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, nurse or pharmacist.

In this leaflet:

1. What Rabies Vaccine BP is and what it is used for
2. Before you are given Rabies Vaccine BP
3. How Rabies Vaccine BP is given
4. Possible side effects
5. How to store Rabies Vaccine BP
6. Further information

1. WHAT RABIES VACCINE BP IS AND WHAT IT IS USED FOR

Rabies Vaccine BP is one of a general group of medicines called vaccines. Vaccines are used to protect against infectious diseases. This vaccine helps to protect adults and children against rabies. Rabies Vaccine BP can be used in two ways:

- Vaccinating you before you come into contact with rabies virus.
- Vaccinating you after you have come into contact with rabies virus.

Rabies Vaccine BP is a preparation containing very small amounts of a modified form of the virus that causes rabies. When an injection of Rabies Vaccine BP is given, the body's natural defences will produce protection against rabies.

2. BEFORE YOU ARE GIVEN RABIES VACCINE BP

To make sure that this vaccine is suitable for you or your child, it is important to tell the doctor, nurse or pharmacist if any points below apply. If there is anything you do not understand, ask your doctor, nurse or pharmacist to explain.

Do not have Rabies Vaccine BP if you or your child is:

- allergic (hypersensitive) to Rabies Vaccine BP or any of its ingredients (see section 6).
- allergic (hypersensitive) to neomycin or betapropiolactone because these are used during vaccine production and may be present in the vaccine in small amounts.
- ill, with a high temperature or acute infection, the vaccination will be postponed until you or your child have recovered.

Your doctor or nurse may still decide to give the vaccine even if any of the above points apply to you or your child. This is because rabies is a serious disease.

Take special care with Rabies Vaccine BP

Tell your doctor or nurse if you or your child:

- has a history of allergy (such as hayfever or asthma) as there may be an increased risk of side effects.
- has had any other reactions to the vaccine when given before. Your doctor will decide whether to continue the course and may decide to do a blood test to see if you or your child are protected.
- has any blood disorders such as haemophilia or thrombocytopenia (a condition where you bruise or bleed easily) because you or your child may get bleeding at the injection site.
- is under 1 year old.

Your doctor or nurse will decide if you or your child should receive the vaccine.

Receiving other vaccines or medicines

Steroids and other medicines that can suppress the immune system can make the vaccine less effective. The doctor may want to test you or your child's blood 2 to 4 weeks after receiving the vaccine to check that it is working properly.

Please tell your doctor, nurse or pharmacist if you or your child are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding

If you are pregnant, think you may be pregnant or breast-feeding tell the doctor or nurse.

There is no evidence that this vaccine affects the unborn baby or the outcome of pregnancy. The doctor or nurse will be able to decide if you should receive the vaccine.

If you have been in contact with rabies, the doctor or nurse will usually decide to give you the vaccine because rabies is a serious disease.

If you have a high risk of coming into contact with rabies in the near future, the doctor or nurse may decide to give you a course of Rabies Vaccine BP to prevent infection.

Ask your doctor, nurse or pharmacist for advice before taking any medicine.

3. HOW RABIES VACCINE BP IS GIVEN

The vaccination will be given by a doctor or nurse. This is because they are trained in the use of vaccines and are equipped to deal with any uncommon severe allergic reaction to the injection.

Dosage

The dose of vaccine that is required depends on whether or not:

- you or your child has previously received the vaccine
- you or your child has come into contact with a rabid or possibly rabid animal

A) Dose before coming into contact with rabies (precautionary / pre exposure):

A total of three injections (1 millilitre each) of the vaccine will be given; one injection on 3 different days.

Injections	Time of injection	Day
First	When you have your first injection	0
Second	7 days after your first injection	7
Third	28 days after your first injection	28

The earliest day that the 3rd dose may be given to be effective is day 21.

If you are at regular or continuing risk of exposure to rabies, a booster injection is required one year after the primary course of 3 injections. Further injections should be given at 3 to 5 year intervals thereafter. If you are a traveller at intermittent risk of exposure to rabies, your doctor or nurse will assess the need for further booster injections in line with official guidance.

Depending on your risk of exposure to rabies, your doctor or nurse may recommend that you have blood tests to check that you have sufficient protection against rabies. Your doctor or nurse will decide whether this is necessary based on official guidance.

As these injections are a precaution, ask your doctor, nurse or pharmacist what you should do if you are bitten by or come into contact with a rabid or possibly rabid animal.

B) Dose if you or your child has had the three injections above, and you or your child has been in contact with a rabid or possible rabid animal:

A total of two injections (1 millilitre each) of the vaccine will be given; one injection on 2 different days.

Injections	Time of injection	Day
First	As soon as possible	0
Second	3 days later	3

Your doctor or nurse will make sure that any bite wounds or scratches are properly cleaned before administering the vaccine.

C) Dose if you or your child are not protected against rabies (have never received rabies vaccine or have not received a full primary course of 3 injections), or if your/your child's history of immunisation is unknown, and you or your child have been in contact with a rabid or possible rabid animal:

A total of five injections (1 millilitre each) of the vaccine will be given; one injection on 5 different days.

Injections	Time of injection	Day
First	As soon as possible	0
Second	3 days after your first injection	3
Third	7 days after your first injection	7
Fourth	14 days after your first injection	14
Fifth	30 (or 28) days after your first injection	30 (or 28)

Your doctor or nurse will make sure that any bite wounds or scratches are properly cleaned before administering the vaccine.

In addition to the 5 injections of Rabies Vaccine BP, your doctor or nurse may also give you or your child an injection of Rabies Immunoglobulin with the first vaccine injection. This substance helps to fight rabies infection immediately, while the injections of the vaccine are starting to work. The decision to give you/your child Rabies Immunoglobulin will be based on official guidance.

How the vaccine is administered

The doctor or nurse will make up and shake the vaccine just before it is given, and will check that the liquid is a pinkish colour and that there are no unexpected particles in it.

The vaccine is given as an injection into a muscle in the upper part of the arm.

The vaccine should not be given into the buttock.

If Rabies Immunoglobulin is also being given, then it will be injected at a different site to the vaccination site.

4. POSSIBLE SIDE EFFECTS

Like all medicines and vaccines, Rabies Vaccine BP can cause side effects, although not everybody gets them.

Serious allergic reactions

Severe allergic reaction (anaphylaxis)

The signs of a severe allergic reaction include:

- difficulty in breathing, blue discolouration of the tongue or lips
- dizziness (low blood pressure) and collapse
- difficulty in swallowing, swelling of the face, lips, tongue and/or throat

If these signs or symptoms occur, they usually develop very quickly after the injection is given and while you are still at the clinic or doctor's surgery.

If any of these symptoms occur after leaving the place where the injection was given, consult a doctor or go to the emergency department of your nearest hospital IMMEDIATELY.

Serum sickness type reaction

- skin rashes, fever, joint pains and enlarged glands

When these symptoms occur, they usually develop 2-4 weeks after receiving the vaccine

If these symptoms occur, consult a doctor as soon as possible.

These types of allergic reaction are more common in patients receiving a booster dose than in patients receiving their first injections.

Other serious side effects

- inflammation of the brain
- fits (convulsion)
- pain or loss of feeling caused by damage to a nerve (neuropathy)
- numbness and weakness of the legs and arms (including an illness called Guillain-Barré Syndrome)
- partial loss of movement, or impaired movement (paresis)

Other Side effects

Very common side effects (reported in more than 1 in 10 people) are:

- pain, redness, swelling/hardness and itching at the site of the injection
- headache
- muscle and/or joint pain
- feeling sick
- diarrhoea
- generally feeling unwell
- chills (shivering)
- swollen glands

Common side effects (reported in less than 1 in 10 people but more than 1 in 100) are:

- dizziness
- stomach pain, being sick (vomiting)
- a high temperature (fever)
- itchy skin, rash - the skin may be raised in patches or wheals may appear.
- difficulty in breathing and wheezing
- bruising at the site of the injection

The following can also occur:

- “pins and needles”, tingling sensations
- lack of energy or strength
- in babies born very prematurely (at or before 28 weeks of gestation) longer gaps than normal between breaths may occur for 2-3 days after vaccination.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, nurse or pharmacist.

Reporting of side effects in the UK

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

Reporting of side effects in Ireland

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517; Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE RABIES VACCINE BP

Keep out of the reach and sight of children.

The vaccine must be stored in a refrigerator between 2°C and 8°C. Do not freeze.

Do not use the vaccine after the expiry date which is stated on the labels and carton after EXP.

The expiry date refers to the last day of that month.

Do not dispose of medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Rabies Vaccine BP contains

Please note that the person who is due to receive the vaccine must tell the doctor or nurse if they have ever had an allergic reaction to any of the ingredients shown below.

- Active ingredient: Inactivated Rabies Virus.....not less than 2.5 International Units per dose (strain PM/WI 38 1503-3M, produced in human diploid MRC-5 cells)
- Human albumin solution (to keep the vaccine stable)
- Water for injections
- Betapropiolactone and an antibiotic called neomycin may be contained in very small amounts because they are used in the manufacture of the vaccine.

What Rabies Vaccine BP looks like and contents of the pack

Rabies Vaccine BP comes in a pack containing a glass, disposable syringe which is filled with 1 millilitre of Water for Injections (with no added preservatives) and a glass vial which contains one dose of the vaccine as a freeze-dried powder. The powder contains small amounts of phenol red. When the Water for Injections is added to the freeze-dried vaccine, phenol red causes it to turn a pinkish colour.

Rabies Vaccine BP is available in packs of one.

Marketing Authorisation Holder

Sanofi Pasteur Europe
14 Espace Henry Vallée
69007 Lyon
France

Distributed by:
United Kingdom:
Sanofi
One Onslow Street
Guildford
Surrey
GU1 4YS
UK
Tel: 0845 372 7101

Ireland:
sanofi-aventis Ireland T/A SANOFI
Citywest Business Campus
Dublin 24
Ireland
Tel: +353 (0) 1 4035 600

Manufacturer

Rabies Vaccine BP is made by:
Sanofi Pasteur,
1541 Avenue Marcel Merieux,
Marcy l'Etoile,
Lyon
France

This leaflet was last approved in 10/2017