PACKAGE LEAFLET: INFORMATION FOR THE USER

Rabies Vaccine BP ≥ 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

Rabies Vaccine BP is indicated for pre-exposure prophylaxis and for post-exposure prophylaxis against rabies in all age groups.

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 (pre-exposure prophylaxis).
- Vaccinating you after you have come into contact with rabies virus (post-exposure prophylaxis).

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 **r**abies.

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.
- has had any allergic reaction to latex. The tip cap of the pre-filled syringe without attached needle contains a natural rubber latex derivative which may cause a severe allergic reaction.

As with all vaccines, Rabies Vaccine BP may not protect 100% of vaccinated people.

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

Receiving other vaccines or medicines

Immunosuppressive treatments, including long-term corticosteroid therapy, may interfere with antibody production and cause the failure of the vaccination. It is therefore advisable to perform a serological test 2 to 4 weeks after the last injection.

Separate injection sites and separate syringes must be used in case of concomitant administration with any other medicinal product, including rabies immunoglobulin.

As rabies immunoglobulin interferes with development of immune response to the vaccine, the recommendations concerning administration of rabies immunoglobulin must be strictly followed.

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, breast-feeding and fertility

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.

The vaccine has not been evaluated for impairment of male or female fertility.

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 recommended dose is 1mL of reconstituted vaccine.

Pre-exposure prophylaxis

The primary pre-exposure immunisation course consists of 3 doses: one at Day 0, Day 7 and either Day 21 or Day 28.

Alternatively, in individuals with a normal immune response, the one-week regimen with 2 doses can be used: at D0 and at D7.

If you are at regular or continuing risk of exposure to rabies, your doctor or nurse will assess the need for further booster injections in line with official guidance.

Post-exposure prophylaxis

Post-exposure prophylaxis should be initiated as soon as possible after suspected rabies exposure.
In all cases, proper wound care (thorough flushing and washing of all bite wounds and scratches the wound with soap or detergent and copious amounts of water and/or virucidal agents) must be performed immediately or as soon as possible after exposure). It must be performed before administration of rabies vaccine or rabies immunoglobulin, when they are indicated.

The rabies vaccine administration must be carried out by appropriately trained medical staff. It must be performed strictly in accordance with the category of exposure, the patient immune status, and the animal status for rabies (according to local official recommendations, see Table 1 for WHO recommendations).

Post-exposure prophylaxis must be performed under medical supervision.

Table 1: WHO category of severity of exposure

Category of exposure	Type of exposure to a domestic or wild animal suspected or confirmed to be rabid or animal unavailable for testing	Recommended post-exposure prophylaxis
I	Touching or feeding of animals Licks on intact skin (no exposure)	None, if reliable case history is available[a]
II	Nibbling of uncovered skin Minor scratches or abrasions without bleeding (exposure)	Administer vaccine immediately Stop treatment if animal remains healthy throughout an observation period of 10 days[b] or is proven to be negative for rabies by a reliable laboratory using appropriate diagnostic techniques. Treat as category III if bat exposure involved.
III	Single or multiple transdermal[c] bites or scratches, contamination of mucous membrane or broken skin with saliva from animal licks, exposures due to direct contact with bats. (severe exposure)	Administer rabies vaccine immediately, and rabies immunoglobulin, preferably as soon as possible after initiation of post-exposure prophylaxis. Rabies immunoglobulin can be injected up to 7 days after administration of first vaccine dose. Stop treatment if animal remains healthy throughout an observation period of 10 days or is proven to be negative for rabies by a reliable laboratory using appropriate diagnostic techniques.

a If an apparently healthy dog or cat in or from a low-risk area is placed under observation, treatment may be delayed.

b This observation period applies only to dogs and cats. Except for threatened or endangered species, other domestic and wild animals suspected of being rabid should be euthanized and their tissues examined for the presence of rabies antigen by appropriate laboratory techniques.

c Bites especially on the head, neck, face, hands and genitals are category III exposures because of the rich innervation of these areas.

Post-exposure prophylaxis of previously non-immunised individuals
Vaccine should be administered on Day 0, Day 3, Day 7, Day 14 and Day 28 (5 injections of 1mL).

For category III exposure (see Table 1), rabies immunoglobulin should be given in association with vaccine. In this case, the vaccine should be administered contra-laterally, if possible.

Vaccination should not be discontinued unless the animal is declared not rabid according to a veterinarian assessment (supervision of animal and/or laboratory analysis).

Post-exposure prophylaxis of previously immunised individuals
Previously immunised individuals should receive one dose of vaccine intramuscularly on both days 0 and 3. Rabies immunoglobulin is not indicated in such cases.

Use in individuals with decreased immunity

- Pre-exposure prophylaxis
  For individuals with decreased immunity, conventional 3-dose regimens should be used (see subsection "Pre-exposure prophylaxis") and serology testing of neutralising antibodies should be performed 2 to 4 weeks after the last dose to assess the possible need for an additional dose of the vaccine.
- Post-exposure prophylaxis
  For individuals with decreased immunity, only a full vaccination schedule should be administered. Rabies immunoglobulin should be given in association with the vaccine for both categories II & III exposures (see Table 1).

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 for intramuscular administration only. The vaccine should be administered into the deltoid muscle for adults and children or the anterolateral area of the thigh muscle in infants and toddlers.
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

Anaphylactic reactions, including shock which can include one or several of the following symptoms:

- itching and skin rash,
- swelling of face and/or neck,
- breathing difficulties, bluish discoloration of the tongue or lips,
- low blood pressure, rapid heart rate and weak pulse, skin coldness, dizziness and potentially fainting.

These symptoms usually appear very soon after the injection.
If one of these symptoms occurs after you have left the place where the injection was given, consult a doctor or go to the emergency department of your nearest hospital IMMEDIATELY.

Other Side effects

Most side effects appeared within 3 days after vaccination and resolved spontaneously within 1 to 3 days after onset. They were reported with the following frequencies:

Very common: may affect more than 1 in 10 people
- Generally feeling unwell
- Headache
- Muscle pain
- Pain at injection site

Common: may affect up to 1 in 10 people
- Fever
- Nausea
- Fatigue, unusual weakness
- Redness at injection site
- Swelling at injection site
- Itching at the injection site
- Bruising at injection site

Uncommon: may affect up to 1 in 100 people
- Allergic reaction with skin or respiratory involvement
- Increase in size of lymph nodes
- Stomach pain
- Diarrhoea
- Vomiting
- Dizziness
- Joint pain
- Chills
- Pins and needles

Rare: may affect up to 1 in 1,000 people
- Swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing

Not known: frequency cannot be estimated from the available data
- Serum sickness disease: joint pain, skin rash, enlarged lymph nodes and generally feeling unwell. When these symptoms appear, it is generally 2-4 weeks after vaccination.
- Swelling or infection of the brain
- Convulsion
- Damage to the nerves which can cause numbness, pain and weakness.

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 or search for MHRA Yellow Card in the Google Play or Apple App Store. 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 label**s** 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
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14 Espace Henry Vallée
69007 Lyon
France

Distributed by:
United Kingdom:
Sanofi
410 Thames Valley Park Drive
Reading
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Manufacturer
Rabies Vaccine BP is made by:
Sanofi Pasteur,
1541 Avenue Marcel Merieux,

Marcy l'Etoile,
Lyon
France

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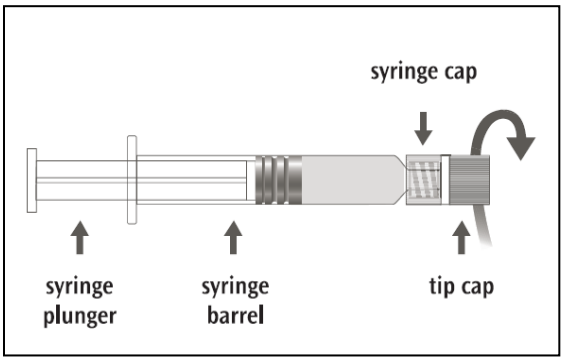
The following information is intended for healthcare professionals only:

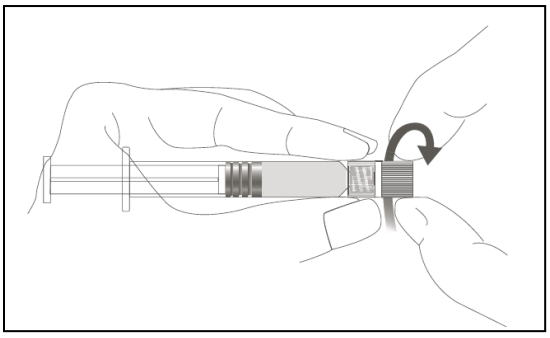
Specific instructions for Luer-lok™ syringe:

- Step 1: Holding the syringe cap in one hand (avoid holding the syringe plunger or barrel), unscrew the tip cap by twisting it counterclockwise.
- Step 2: To attach the needle to the syringe, gently twist the needle clockwise into the syringe until slight resistance is felt.

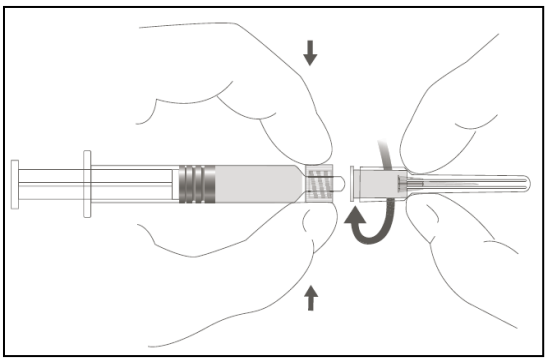
Picture A: Luer-Lok™ syringe



Picture B: Step 1



Picture C: Step 2



- To reconstitute the freeze-dried vaccine: introduce the solvent into the vial of powder and gently swirl until complete suspension of the powder is obtained. The suspension should be clear or slightly opalescent, red to purple-red in colour.
- Without removing the needle from the vial, unscrew the syringe to eliminate negative pressure (as the vial is sealed under vacuum). Re-attach the needle remaining in the vial to the syringe (as per step 2).
- Withdraw the total contents of the vial into the syringe.
- Unscrew the reconstitution needle and replace it with a sterile needle (as per step 2) of a proper length for intramuscular injection of your patient. Inject immediately.

The vaccine must be visually inspected before any administration in order to make sure there are no foreign particles in the vaccine.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.