

Reason for Update: Type IAIN-addition of Bavarian Nordic as alternative release site (As this does not impact the artwork, date of revision and trademark date will not be updated)

Market: IE

Agency Approval Date: 01 Sept 2020

Text Date: 07/08/2020

Issue No.: 6

Draft No.: 1

PACKAGE LEAFLET: INFORMATION FOR THE USER

Rabipur

Powder and solvent for solution for injection in pre-filled syringe
Rabies virus (Inactivated, strain Flury LEP)

Read all of this leaflet carefully before you/your child receives Rabipur. It contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, or nurse.
- This vaccine has been prescribed for you/your child only. Do not pass it on to others.
- If you get any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What **Rabipur** is and what it is used for
2. What you need to know before you/your child receives **Rabipur**
3. How to use **Rabipur**
4. Possible side effects
5. How to store **Rabipur**
6. Contents of the pack and other information

1 WHAT RABIPUR IS AND WHAT IT IS USED FOR

What Rabipur is

Rabipur is a vaccine containing rabies virus that has been killed. After administration of the vaccine, the immune system (the body's natural defence system) forms antibodies to rabies viruses. These antibodies protect from infections or diseases by the virus that causes rabies. None of the components of the vaccine can cause rabies.

What Rabipur is used for

Rabipur can be used in individuals of all ages.

Rabipur can be used to prevent rabies:

- before possible risk of exposure to rabies virus (pre-exposure prophylaxis).
- or
- after suspected or proven exposure to rabies virus (post-exposure prophylaxis).

Rabies is an infection that can be transmitted when a person is bitten, scratched or even just licked by an infected animal, particularly when the skin is already injured. Even contact with animal traps that were licked or bitten by infected animals can cause infections in humans.

2 WHAT YOU NEED TO KNOW BEFORE YOU/YOUR CHILD RECEIVES RABIPUR

You/Your child must not receive Rabipur before possible risk of exposure to the rabies virus if you/your child:

- Have/has a history of having a severe allergic reaction to the active substance or any ingredient of the vaccine listed in **section 6**.

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- Have/has an acute disease requiring treatment.

Because of the seriousness of rabies infection, Rabipur can be given to anyone if they have been exposed to rabies, even those who are pregnant.

Severe allergic reactions (hypersensitivity)

If you or your child is known to be at risk of a severe allergic reaction to the vaccine or to any of the ingredients, you/your child may be given a different vaccine against rabies that does not contain these ingredients. If there is no alternative vaccine available, your doctor or nurse will discuss the risks of vaccination and rabies virus infection with you before you or your child receives the vaccine.

Warnings and precautions

In case of acute disease requiring treatment, vaccination is usually postponed until at least 2 weeks after recovery. The presence of a minor infection should not require postponement of the vaccination, but talk to your doctor or nurse first.

Tell your doctor or nurse before you or your child receives Rabipur for post exposure prophylaxis if you/your child:

- Have/has a severe allergy to egg or egg products (for symptoms see **section 4** of this leaflet). Rabipur contains residues of chicken proteins left over from the manufacturing process.
- Have/has a severe allergy to the antibiotics neomycin, chlortetracycline, or amphotericin B. These antibiotics may be present in very small amounts in the vaccine.
- Have/has a severe allergy to polygeline.

Fainting can occur following, or even before, any needle injection, therefore tell the doctor or nurse if you fainted with a previous injection.

Cases of very rare but severe conditions affecting the nervous system have been reported following the receipt of Rabipur vaccine. See **section 4**. Anti-inflammatory medicines (steroids), often used to treat these conditions, may interfere with the effectiveness of the vaccine (see below, *other medicines and Rabipur*). Your doctor or nurse will decide how to proceed in this circumstance.

As with all vaccines, Rabipur may not fully protect all people who are vaccinated.

The vaccine should not be given into the buttocks, under the skin or into a blood vessel.

Other medicines and Rabipur

Tell your doctor or nurse if you are /your child is taking, have/has recently taken, or plan to take any other medicines, even those not prescribed. Unless your doctor tells you otherwise, you/your child should continue to take all prescribed medicines as usual.

If you or your child already has a poor immune system or is already taking medicines that reduce the body's immunity to infections, Rabipur can still be given but you/your child may not be as well protected as other people. In this case, your/your child's doctor may decide to carry out blood tests after the vaccine administration, to check if the body has produced enough antibodies to the virus. If necessary, you/your child will be given extra doses of the vaccine (see **section 3** of this leaflet).

Rabipur can be given at the same time as other inactivated vaccines. A different injection site will be used for each type of vaccine.

You/Your child may also need to be given an injection of antibodies against rabies (called "**rabies immunoglobulin**") if you or your child have not been fully vaccinated against rabies and it is very likely that you or your child has been infected with the virus. If so, the rabies immunoglobulin injection (given

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only **once** and usually with the first dose of the vaccine) and the vaccine will be given **in different parts** of the body.

Pregnancy and breast-feeding

If you are pregnant or breastfeeding, if you think you may be pregnant, or are planning to have a baby, you should still be given rabies vaccine if you have had, or are likely to have had, contact with the virus. You can also be vaccinated with Rabipur during pregnancy or while breastfeeding and before exposure to the virus, if the risk of contact with the virus is thought to be considerable. In this instance, your doctor will discuss the risks of vaccination and rabies infection with you and advise on the best timing of Rabipur vaccination.

Driving and using machines:

Some of the adverse effects described in **section 4** of this leaflet may affect the ability to drive and use machines.

Rabipur contains:

Less than 23 mg of sodium per dose, and is therefore essentially 'sodium- free'.

3. HOW TO USE RABIPUR

Rabipur will be given to you/your child by a doctor or nurse who has been trained to give vaccines. Treatment that may be needed to manage very serious types of allergic reactions that can occur after receipt of the vaccine should be available (see **section 4** of this leaflet). The vaccine should be given to you/your child in a clinic or surgery that has the necessary equipment to treat these reactions. Instructions intended for doctors and medical personnel for reconstituting the vaccine can be found at the end of this leaflet.

The recommended dose for adults and children of any age is one millilitre (1.0 ml) per injection.

Your doctor will decide how many doses you/your child should receive; this will depend on whether you/your child are/is being given Rabipur before or after any possible contact with the virus.

The vaccine is given as an injection into a muscle (usually in the upper arm, or in small children, into the muscle of the thigh).

BEFORE ANY POSSIBLE CONTACT WITH THE VIRUS

If you have/your child has never had any rabies vaccine before:

- you need to have 3 doses in the first instance. The first dose is given at the first visit, the second dose is given 7 days later and the third dose 21 or 28 days after the first dose.
- if you are an adult between 18 and 65 years of age needing a rapid protection, Rabipur can also be given to you as a total of three doses over 7 days. The first dose is given at the first visit, the second dose is given 3 days later and the third dose 4 days after the second dose.

If you/your child miss an appointment for an injection, you should arrange to have it as soon as possible after the due date.

The need for boosters depends on the risk of contact with rabies virus. Your doctor will consult the official recommendations on rabies vaccination and will tell you when a booster is needed.

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If you are at continuous high risk of infection, your doctor may also ask you to have regular blood tests to measure the amount of antibody against rabies in your blood so that boosters can be given as soon as needed. Experience shows that booster doses are generally required every 2-5 years.

AFTER SUSPECTED OR PROVEN CONTACT WITH THE VIRUS

Vaccinated people

If you have/your child has already been fully vaccinated against rabies and/or have received boosters, and have been in contact with a rabid or suspected rabid animal, you/ your child usually need 2 more doses of vaccine (1.0 ml each). The first dose is given as soon as possible after the contact, and the second is given 3 days later.

Unvaccinated people

If you/your child have/has not been vaccinated before or received inadequate basic immunization, either 4 or 5 doses (1.0 ml each) will be given according to one of the following schedules:

- If an immunization schedule of 4 doses is used, the first 2 vaccine doses are given as soon as possible after the contact on day 0 and then single doses are given 7 and 21 days after the first dose.
- An alternative 4 doses schedule can be adopted as well for healthy people who are known to have a good immune response; the first vaccine dose given as soon as possible after the contact on day 0 and the others given on days 3, 7 and 14 after the first dose
- If an immunization schedule of 5 doses is used, the first vaccine dose is given as soon as possible after the contact on day 0 and the others are given on days 3, 7, 14 and 28 after the first dose.

After any possible contact with rabies virus, your doctor will consider the risk of infection according to the type of contact you have/your child has had. For example, if you have been bitten or scratched by an animal that could have the virus, or have been in contact with bats, you are at much greater risk of rabies infection than someone who has been licked but has no break in the skin.

People with a compromised immune system (poor immunity to infection)

If you have/your child has an increased risk of rabies infection because your immune system is not working properly, you/your child will need five or six doses (each of 1.0 ml) of rabies vaccine after contact with a rabid or suspected rabid animal. Vaccination is given in combination with local treatment of the wound and rabies immunoglobulin.

If six doses are used, the first two are given as soon as possible after the contact, and then single doses are given on days 3, 7, 14 and 28 after the first dose.

If five doses are used, the first dose is given as soon as possible after the contact, and the others are given on days 3, 7, 14 and 28 after the first dose.

It may also be necessary for you/your child to have blood tests to measure the amount of antibody to rabies virus in your/your child's blood so that extra doses of vaccine can be given if needed. Your doctor will explain what needs to be done and will tell you when to attend for extra tests or doses.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious allergic reactions involving the whole body, sometimes associated with shock (dangerously low blood pressure)* can occur following Rabipur vaccination. Appropriate medical treatment and supervision should always be readily available in case of a rare severe allergic reaction to the vaccine. Talk to a doctor straight away if they happen.

The most common side effects reported with the use of Rabipur were pain at the injection site, mainly pain due to the injection, or hardness of the skin at the site of injection. These reactions are very common (occurring

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in more than 1 in 10 persons). Most injection site reactions were not severe and resolved within 24 to 48 hours after injection.

Other side effects include:

Very common (these may affect more than 1 in 10 people)

Headache

Dizziness

Rash

General discomfort

Fatigue,

Weakness

Fever

Common (these may affect up to 1 in 10 people)

Swollen glands

Decreased appetite

Nausea

Vomiting

Diarrhoea

Stomach pain/discomfort

Hives

Muscles pain

Joint pain

Rare (these may affect up to 1 in 1,000 people)

Allergic reactions

Pins and needles or tingling sensations

Sweating

Chills

Very rare (these may affect up to 1 in 10,000 people)

Inflammation of the brain, nerve disturbances that can cause weakness, inability to move or loss of feeling in some parts of the body*

Fainting, unsteadiness with dizziness*

Serious allergic reaction which causes swelling of the face or throat*

*Description of adverse reactions from spontaneous reporting

Additional side effects in children

Frequency, type and severity of adverse reactions in children are expected to be the same as in adults.

Reporting of side effects

If you or your child get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

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Ireland

HPRa Pharmacovigilance

Website: www.hpra.ie

5. HOW TO STORE RABIPUR

Keep this vaccine out of the sight and reach of children.

Store protected from light in a refrigerator (at 2°C to 8°C). Do not freeze.

Keep the vial and the syringe in the outer carton in order to protect from light.

Do not use this vaccine after the expiry date which is stated on the outer carton. The expiry date refers to the last day of the month. Do not throw away any vaccine via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Rabipur contains

The active substance in the vaccine is rabies virus (inactivated, strain Flury LEP) ≥ 2.5 IU. This has been produced on purified chick embryo cells (PCEC).

The other ingredients are: trometamol, sodium chloride, disodium edetate, potassium-L-glutamate, polygeline, sucrose and water for injections.

Chicken proteins (e.g., ovalbumin), human serum albumin, neomycin, chlortetracycline, amphotericin B are present as residues.

What Rabipur looks like and contents of the pack

Rabipur is a white freeze-dried powder to be reconstituted with the clear colourless solvent. The reconstituted vaccine is clear to slightly opalescent and colourless to slightly pink.

Rabipur is supplied in packs containing 1 vial of the powder, 1 disposable pre-filled syringe of sterile diluent with 1 small orange needle for injection and one long green needle for reconstitution.

Marketing Authorisation Holder:

GSK Vaccines GmbH

Emil-von-Behring-Str. 76

35041 Marburg

Germany

Manufacturer:

Bavarian Nordic A/S

Hejreskovvej 10A

3490 Kvistgaard

Denmark

GSK Vaccines GmbH

Emil-von-Behring-Str. 76

35041 Marburg

Germany

Other formats:

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK Only)

Please be ready to give the following information:

Product name **Rabipur**

Reference number 16033/0010

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This is a service provided by the Royal National Institute of Blind People.

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria	Rabipur
Belgium	Rabipur
Bulgaria	Rabipur
Croatia	Rabipur
Denmark	Rabipur
France	Rabipur
Germany	Rabipur
Hungary	Rabipur
Ireland	Rabipur
Italy	Rabipur
Luxembourg	Rabipur
Netherlands	Rabipur
Norway	Rabipur
Poland	Rabipur
Portugal	Rabipur
Spain	Rabipur
Sweden	Rabipur
United Kingdom	Rabipur

This leaflet was last revised in July 2019

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The following information is intended for healthcare professionals only:

Instruction for use of Rabipur disposable pre-filled syringe
Pre-filled syringe

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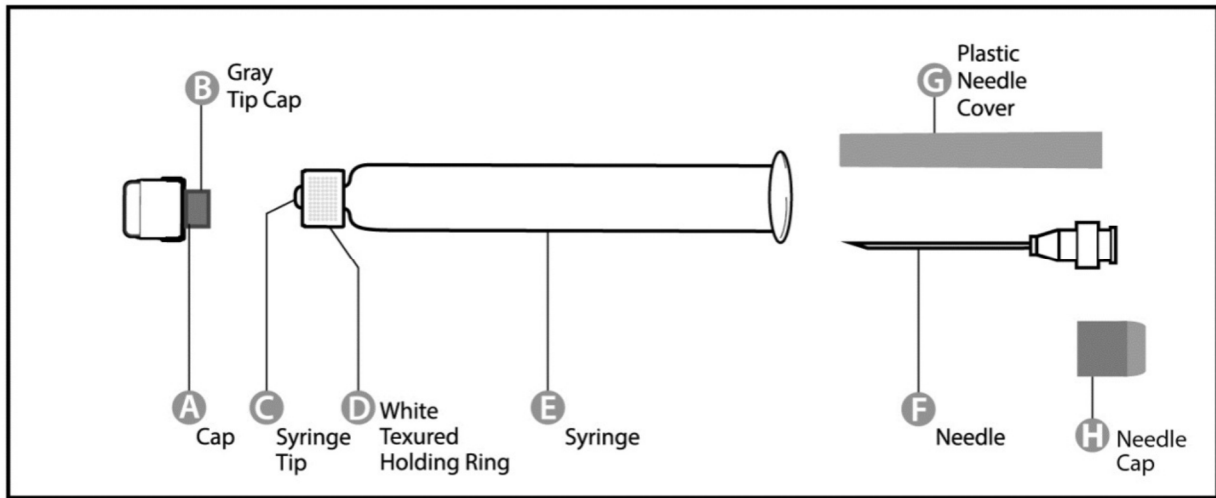
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<p>Step 1: With one hand, hold the syringe (E) with the cap pointing upward. Be sure to hold the syringe by the white textured holding ring (D).</p>	
<p>Step 2: With the other hand, grasp the cap (A) and firmly rock it back and forth to break its connection to the holding ring (D). Do not twist or turn the cap.</p>	
<p>Step 3: Lift up to remove the cap (A) and the attached gray tip cap (B). Be careful not to touch the sterile syringe tip (C).</p>	

Needle application (these instructions apply to both the green and the orange needles):

<p>Step 1: Twist to remove the cap (H) from the green reconstitution needle. Do not remove the plastic cover (G). This needle is the longer of the two needles.</p>	
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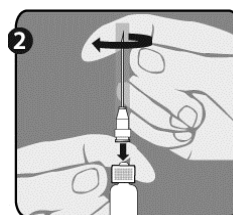
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Step 2: With one hand, firmly hold syringe (E) by white textured holding ring (D). With your other hand, insert needle (F) and twist clockwise until it locks into place. Once needle is locked, remove its plastic cover (G).
The syringe is now ready for use.



Instructions for reconstituting Rabipur with the use of pre-filled syringe:

The vaccine should be visually inspected both before and after reconstitution for any foreign particulate matter and or change in physical appearance. The vaccine must not be used if any change in the appearance of the vaccine has taken place. The reconstituted vaccine is clear to slightly opalescent and colourless to slightly pink.

The powder for solution should be reconstituted using the solvent for solution supplied and carefully agitated prior to injection. The reconstituted vaccine should be used immediately.

The vial of vaccine contains negative pressure. After reconstitution of the vaccine, it is recommended to unscrew the syringe from the needle to eliminate the negative pressure. After that, the vaccine can be easily withdrawn from the vial. It is not recommended to induce excess pressure, since over-pressurization will create the problems in withdrawing the proper amount of the vaccine.

After completing the reconstitution of the vaccine, remove the cap from the orange administration needle (as explained in step 1 for the green needle) and replace the green reconstitution needle with the orange administration needle or other appropriate needle.