PATIENT INFORMATION LEAFLET

Read all of this leaflet carefully before you receive this vaccine.
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

In this leaflet:

The full name of the vaccine is **Rabipur**
Powder and solvent for solution for injection

- 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.
- The other ingredients are TRIS-(hydroxymethyl)-aminomethane, Sodium chloride, Disodium edetate (Titriplex III), Potassium-L-glutamate, Polygeline, Sucrose and Water for Injections. Traces of neomycin, chlortetracycline, amphotericin B and chick proteins may be present.
- The solvent for solution for injection is 1 ampoule of water for injections (1 ml) BP (Martindale PL 1883/6160R or CSL Behring PL 15036/0015).

Marketing Authorisation Holder and Manufacturer:
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1. WHAT RABIPUR IS AND WHAT IT IS USED FOR

Rabipur is supplied as lyophilised powder and solvent for solution for injection. Each dose of one millilitre contains ≥ 2.5 IU rabies virus antigen. Rabipur is supplied in packs containing 1 vial of the powder, 1 ampoule of sterile water and 1 disposable syringe with separate needle.

Rabipur is one of a group of medicines called vaccines that interact with the immune system (the body's natural defence against infections) to protect against diseases in the future. Rabipur is used to prevent or treat infection by the virus that causes rabies.
Rabies vaccine works by causing your body to produce its own protection (antibodies) against the virus. The vaccine contains rabies viruses that have been inactivated by chemical processing so that the vaccine cannot cause rabies but the viruses in it can still cause the immune system to make antibodies to them.

Rabipur can be used in 2 ways:

- to prevent rabies in people who may be at risk of catching the virus in the future. For example, people who work with animals or are travelling to parts of the world where rabies cases are known to occur.

or

- to treat people who are likely to have caught the virus already through contact with live or dead animals, as described below.

Rabies is an infection that can be caught by being bitten by an infected animal or by being scratched or even just licked by an animal, especially if the skin is already broken. Contact with animal snares that have been licked or bitten by infected animals can also cause infections in humans.

Animals that are perfectly well in themselves can carry the virus and pass it on to humans. These animals may or may not go on to develop rabies themselves. Contact with the carcasses of dead infected animals is also sometimes a way of catching the disease.

There is no treatment for rabies once there are symptoms of the infection present and in these cases the infection is always fatal. Prevention of the development of symptoms of infection and death depends on vaccination either before any possible contact with the virus or as soon as possible after contact with the virus, even if only suspected.

2. BEFORE YOU HAVE/YOUR CHILD HAS RABIPUR

When Rabipur is intended for use before any possible contact with the virus, it must not be given if the answer to any of the following questions for the person who is to have the vaccine is "YES". If you are not sure about anything, ask your doctor or nurse before the vaccine is given**.**

- Are you /is your child allergic to any ingredient of the vaccine? Please remember that the vaccine may contain very small amounts of neomycin, chlortetracycline or amphotericin B. It may also contain traces of chick proteins so that people who are allergic to eggs and egg products could be allergic to this vaccine.
- Do you /does your child have a feverish illness at the moment? Vaccination is usually postponed until the fever has gone but you may still have the vaccine if you have only a mild infection and low fever.

If you have already been in contact with the virus and so may be infected, you may be given the vaccine even if the answer to either of the questions above is "YES". This is because rabies is such a serious infection. However, if you are known to be allergic to any of the ingredients, your doctor or nurse may be able to give you a different vaccine against rabies that does not contain these ingredients. If there is no alternative vaccine for you, your doctor or nurse will discuss the risks of vaccination and the risks of rabies infection with you before you have the vaccine.

Pregnancy:

If you are or think you may be pregnant, you should still be given rabies vaccine if you have had or are thought likely to have had contact with the virus.

You can also have Rabipur while you are pregnant before any possible contact with the virus if the risk of contact is thought to be considerable. In this instance, your doctor or nurse can advise you whether to have rabies vaccine now or to wait.

Breast-feeding:
Rabipur should still be given if you have had or are thought likely to have had contact with the virus. You can also have Rabipur while you are breastfeeding before any possible contact with the virus if the risk of contact is thought to be considerable. Your doctor or nurse can advise you.

Driving and using machines:
The vaccine is unlikely to produce an effect on your ability to drive and use machines.

Using other medicines and having other vaccines:
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed. Unless your doctor tells you otherwise, you should continue to take all prescribed medicines as usual.

If you have a poor immune system for any reason, including taking medicines that reduce your immunity to infections, you can still have Rabipur but you may not be as well protected as other people. In this case, your doctor may decide to carry out blood tests after you have received the vaccine to check if you have made enough antibody to the virus. If necessary you will be given extra doses of the vaccine.

You can have Rabipur at the same time as other vaccines that do not contain live bacteria or viruses (including tetanus vaccine) if this is necessary.

You may also need to have an injection of antibody against rabies (called rabies immunoglobulin) at the same time as Rabipur if you are very likely to have already caught the virus. If so, the rabies immunoglobulin injection (which is given only once and usually with the first dose of the vaccine) and the vaccine will be given into separate body sites. Usually, as much as possible of the rabies immunoglobulin is injected into the area of the body that came into contact with the animal and any that is left is given as a separate injection.

3. HOW RABIPUR IS GIVEN

Rabipur will be given to you by a doctor or nurse who has been trained to give vaccines. They should also have been trained to deal with the very rare but serious types of allergic reactions that can occur (see section 4 of this leaflet) and the vaccine should be given in a clinic or surgery that has the necessary equipment to treat these reactions.

The powder will be mixed with the water to make a solution before the injection is given. Once mixed, the recommended dose for each injection is one millilitre (a small amount of liquid) in all age groups. The vaccine will usually be given into the muscle of the upper arm or, in small children, into the muscle of the thigh. The vaccine should not be given into the buttocks. Your doctor or nurse will take care that the vaccine is not given into the skin or into a blood vessel.

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 (clear colourless solution) of the vaccine has taken place.

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

How many doses you should receive depends on whether you receive Rabipur before or after any possible contact with the virus.

DOSES BEFORE ANY POSSIBLE CONTACT WITH THE VIRUS

People who have never had any rabies vaccine before need to have three doses in the first instance. The first dose is given at the first visit, the second 7 days later and the third dose 2-3 weeks after that. If you miss an appointment for an injection, you should arrange to have it as soon as possible after the due date.

Once the first three doses have been completed, people who continue to be at risk of catching rabies will need booster doses at intervals to keep up their antibody levels against rabies.

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 you need to have a booster. For people who may be at 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.

If you have had all the injections due and have kept up with regular boosters, you may still need to have extra injections if you actually come into contact with the virus and the risk of infection is thought to be high. This is explained below.

DOSES AFTER ANY POSSIBLE CONTACT WITH THE VIRUS

After any possible contact with rabies virus, your doctor will consider the risk of infection according to the type of contact you have had. For example, people who have been bitten by an animal that could have the virus are at much more risk of rabies infection than people who have been licked but have no break in the skin.

When vaccination is considered to be necessary, the first dose will be given as soon as possible and any wound will also be treated with an antiseptic.

The number of doses of vaccine that you will be given, with or without rabies immunoglobulin (extra antibody against rabies virus to increase immediate protection) depends on the risk of catching rabies and whether you have had any doses of rabies vaccine before. . Also, people who have an increased risk of catching the virus because their immune system is not working properly or have wounds that are especially likely to lead to infection need special attention as explained below.

Remember that rabies can be a fatal infection.

In all cases, it is very important that you attend on time for all the doses of vaccine that you need (see below) and for any blood tests that your doctor may say are necessary. If you are late for any appointment you must attend as soon as possible. If you are unwell at any time while you are having the course of vaccinations you must let your doctor know immediately and must not miss any injections.

People who have been vaccinated against rabies and have kept up their boosters over time usually need only two extra doses. One is given immediately and the second is given three days later. However, if the last dose of vaccine was more than two years ago, it may be necessary to give four or five doses as for unvaccinated people (see below).

For people who have not been vaccinated before or who have not been vaccinated for some time or who have received certain types of rabies vaccine in the past that may give lower protection than those that are now in use in most countries, either four or five doses can be given. If four doses are used, the first two are given immediately and then single doses are given one and three weeks later. If five doses

are used, the first dose is given immediately and the others are given on days 3, 7, 14 and 28 after the first dose.

People who have poor immunity to infections for any reason, those with several wounds from animal contact, with wounds on the head and neck or who could not get medical attention until some while after the possible contact with rabies virus all need special care.
It is usual that these people all get at least five doses of vaccine, at the times described above. Sometimes an extra dose is given immediately so that six injections are given over four weeks. These people are more likely to need to have rabies immunoglobulin as well as vaccinations. It may also be necessary for these people to have blood tests to measure the amount of antibody to rabies virus in the 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, Rabipur can have side effects.

Serious allergic reactions are always a rare possibility after receiving a vaccine. These reactions may include difficulty in breathing, blue discolouration of the tongue or lips, swelling of the face and neck or elsewhere, and low blood pressure causing collapse and shock. When these signs or symptoms occur they usually develop very quickly after the injection is given and while the person affected is still in the clinic or doctor's surgery. If any of these symptoms occur after leaving the place where your injection was given, you must consult a doctor IMMEDIATELY. These types of allergic reactions are rare (occur in less than one in a thousand persons vaccinated).

Other less serious allergic reactions include rashes that may be red and lumpy and also itchy. These can occur in less than one in ten but more than one in a hundred persons vaccinated.

<u>Other possible side effects are:</u>
Very common (occurring in more than one in ten persons): pain, swelling and other reactions at the site of the injection.

Common (occurring in more than one in a hundred but less than one in ten persons): reddening at the injection site, weakness, generally feeling unwell, fever, tiredness, flu-like illness, swollen glands, headache, muscle pain, joint pain and digestive upsets such as feeling sick and stomach pains.

Rare (occurring in more than one in ten thousand but less than one in thousand persons): disturbances in blood circulation (which may cause symptoms like palpitations or hot flushes), problems with vision, or pins and needles or tingling sensations.

Very rare (occurring in less than one in ten thousand persons): unsteadiness with dizziness, nerve disturbances that can cause weakness, inability to move or loss of feeling in some parts of the body.

If you notice any other effects not listed above, please tell your doctor, nurse or pharmacist (chemist).

5. STORING RABIPUR

Your doctor or nurse should store this vaccine in its original packaging at 2°C – 8°C (in a refrigerator). They will check that the vaccine has not passed the expiry date printed on the label. Your doctor or nurse should make sure that this vaccine is kept out of the reach and sight of children.

This leaflet was last approved on August 2007