PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

CHIRORAB freeze dried suspension

Inactivated rabies virus (strain flurry LEP, potency) ≥ 2,5 IU per 1,0 ml

Contains sugar (sucrose): 20,0 – 100,0 mg.

Sodium: 4,0 – 5,0 mg

Read all of this leaflet carefully before you are given CHIRORAB

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.

What is in this leaflet

1. What CHIRORAB is and what it is used for

CHIRORAB is a vaccine containing rabies virus that has been killed. It is used in people of all ages to prevent against or treat infection by the virus that causes rabies.

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.

CHIRORAB can be used in 2 ways

- to prevent rabies before possible risk of exposure to rabies virus (pre-exposure prophylaxis), or
- to treat people 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 or your child are given CHIRORAB

CHIRORAB should not be administered to you or your child:

- If you/your child are hypersensitive (allergic) to the active substance or any of the other ingredients of CHIRORAB (listed in section 6).
- If you/your child have an acute disease requiring treatment. Vaccination is usually postponed until at least 2 weeks after recovery. The presence of a minor infection, such as a cold, should not require postponement of the vaccination, but talk to your doctor or nurse first.

After suspected or proven exposure to rabies virus you may be given CHIRORAB

- if you are/your child is allergic to any ingredients of the vaccine, or has an acute disease requiring treatment. This is because rabies is such a serious disease
- pregnant or breastfeeding women may be vaccinated with CHIRORAB to treat rabies infection after suspected or proven exposure to rabies virus.

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 infection with you before you or your child receives the vaccine.

Warnings and precautions

Special care should be taken with CHIRORAB

Severe allergic reactions including anaphylactic shock (a life-threatening allergic response involving the whole body and in which blood pressure falls dangerously low) have occurred following CHIRORAB vaccination.

As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of a rare severe allergic reaction to the vaccine.

Talk to your doctor, pharmacist or nurse before you/your child receives CHIRORAB if you/your child:

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

Cases of very rare but severe conditions affecting the nervous system have been reported following the receipt of CHIRORAB 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 CHIRORAB). Your doctor or nurse will decide how to proceed in this circumstance.

Other medicines and CHIRORAB

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

If you/your child already has a poor immune system or is already taking medicines that reduce the body's immunity to infections, CHIRORAB 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).

You/your child may also need to be given an injection of antibodies against rabies (called "rabies immunoglobulin") if you/your child have not been fully vaccinated against rabies and it is very likely that you/your child have been infected with the virus. If so, the rabies immunoglobulin injection (given only once and usually with the first dose of the vaccine) and the vaccine will be given in different parts of the body.
Usually, as much as possible of the rabies immunoglobulin is injected into the area of the body that came into contact with the animal. Any remaining immunoglobulin is given to you at a separate injection site.

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

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider before CHIRORAB is given to you. 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 CHIRORAB 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 advice on the best timing of CHIRORAB vaccination.

Driving and using machines

It is not known whether the vaccine has an effect on your ability to drive or use machines. However, some of the adverse effects, e.g. headache and dizziness, described in section 4 of this leaflet may affect the ability to drive and use machines.

CHIRORAB contains sucrose; a form of sugar and sodium

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking CHIRORAB.

CHIRORAB contains sucrose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

CHIRORAB contains less than 1 mmol sodium (23 mg) per 1,0 ml dose and is therefore essentially ‘sodium-free’.

3. How CHIRORAB is administered

You will not be expected to give CHIRORAB to yourself. It will be given to you by a person who is qualified to do so. 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). The

vaccine should be given to you/your child in a clinic or surgery that has the necessary equipment to treat these reactions.

Dosage in adults and children

CHIRORAB can be used in individuals of all ages.

The recommended dose is 1,0 ml when injected into the muscles; intramuscular (IM) or 0,1 ml injected into the skin; intradermal (ID).

CHIRORAB is usually given into a muscle (usually in the upper arm or, in small children, into the muscle of the thigh) or into the skin. CHIRORAB should not be given into the buttocks, under the skin or into a blood vessel.

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

Before any possible contact with the virus

If you have/your child have never had any rabies vaccine before, you/your child will need to have overall 3 doses on days 0, 7 and 21 (or 28).

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

Vaccination with rabies vaccine before any possible contact with the virus is recommended for anyone who is at continual, frequent or increased risk for exposure to the rabies virus, as a result of their residence or occupation, such as laboratory workers dealing with rabies and other similar viruses, veterinarians and animal handlers. Travellers in high-risk areas should consult their doctor or nurse for advice on vaccination with the rabies vaccine.

Children living in or visiting rabies-affected areas are at particular risk.

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

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 antibodies 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 to 5 years.

After any possible contact with the virus

Vaccinated people: If you have/your child have already been fully vaccinated against rabies and/or have received boosters, and have been in contact with a suspected animal, you/your child usually need 2 more doses of vaccine (1,0 ml each if the vaccine is given into a muscle or 0,1 ml each if the vaccine is given into the skin). 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, you/your child may be given CHIRORAB by injecting into the muscle (1,0 ml for each dose) following either a 4-dose, or 5-dose treatment schedule:

- 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
- 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.

You/your child may also be given CHIRORAB by injecting into the skin (0,1 ml for each dose) following a 8-dose treatment schedule:

- 2 vaccine doses are given as soon as possible after the contact on day 0 at different parts of your body (e.g. upper arm and thigh), followed by 2 doses each at different parts of your body, at day 3, 7 and 28 after the first dose.

Alternatively, you/your child may be given a 14-dose treatment into the skin:

- 1 vaccine is given at each of the following 8 sites: the left and right upper arms and thighs,

shoulder regions and lower quadrants of the stomach on day 0, one vaccine at each 4 sites: the left and right upper arms and thighs on day 7 and 1 vaccine on the upper arm on day 28 and day 90

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

When vaccination is necessary, the first dose will be given as soon as possible and any wounds will be treated locally as follows:

- thorough flushing and washing of the wound with soap and water
- applying povidone iodine or other antiseptic to the wound
- if soap or antiseptic are not available, the wound should be thoroughly and extensively washed with water.

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

If you/your child have an increased risk of catching the virus because your immune system is not working properly or you/your child have wounds that are especially likely to lead to infection, you/your child will need five or six doses of rabies vaccine (1,0 ml given into a muscle) 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 immediately, 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 immediately, 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.

If more CHIRORAB is administered than is required

Since a healthcare professional will administer CHIRORAB, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you have any further questions on the use of this medicine, ask your doctor, nurse or pharmacist

4. Possible side effects

CHIRORAB can have side effects.

Not all side effects reported for CHIRORAB are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking CHIRORAB, please consult your health care provider for advice.

If any of the following happens, tell your doctor immediately or go to the casualty department at your nearest hospital:

- Serious allergic reactions involving the whole body, sometimes associated with shock (dangerously low blood pressure) can occur following CHIRORAB 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 CHIRORAB 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 in more than 1 in 10 persons). Most injection site reactions were not severe and resolved within 24 to 48 hours after injection.

Tell your doctor if you notice any of the following:

Frequent

- swollen glands (lymphadenopathy)
- decreased appetite
- headache, dizziness
- nausea, vomiting, diarrhoea, stomach pain/discomfort
- rash, hives (urticaria)
- muscles pain, joint pain (myalgia, arthralgia)
- injection site reactions, general discomfort, (malaise), fatigue, weakness (asthenia), fever.

Less frequent

- allergic reactions, which can include selling of the face and throat.
- pins and needles or tingling sensations (paraesthesia)
- fainting, unsteadiness with dizziness
- sweating (hyperhidrosis)
- chills.

Frequency unknown

- inflammation of the brain(encephalitis), nerve disturbances that can cause weakness inability to move or loss of feeling in some parts of the body (Guillain-Barré syndrome),
- swelling of face and throat (angioedema)

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

By reporting side effects, you can help provide more information on the safety of CHIRORAB.

5. How to store CHIRORAB

- Store all medicines out of reach of children
- Store between 2 °C to 8 °C.
- Protect from light.
- Do not freeze. After reconstitution CHIRORAB is to be used immediately.
- Discard any unused portion after use.
- CHIRORAB should not be used after the expiration date on the package and container.

Reconstitution: Only a trained healthcare professional should prepare the solution for infusion. Once CHIRORAB has been prepared, it should be used straight away and any unused portion discarded.

6. Contents of the pack and other information

What CHIRORAB contains

- The active substance is rabies virus (inactivated, strain Flury LEP) ≥ 2,5 IU. This has been produced on purified chick embryo cells (PCEC).
- The other ingredients are:

  Powder: Disodium edetate, polygeline, potassium-L-glutamate, sodium chloride, sucrose, TRIS-(hydroxymethyl)-aminomethane.

  Solvent: Water for injection.

  Residue present in active substance: Chicken proteins (e.g., ovalbumin), human serum albumin, and may contain traces of neomycin, chlortetracycline and amphotericin B.

What CHIRORAB looks like and contents of the pack

CHIRORAB is a white, freeze-dried vaccine for reconstitution with the solvent prior to use.

The solvent is clear and colourless.

A clear colourless solution results after reconstitution of the white freeze-dried powder with the clear and colourless solvent.

Package with 1 clear vial (type I glass) of freeze-dried vaccine with stopper (chlorobutyl) 1 clear glass ampoule (type I glass) Sterile Water for Injection (1,0 ml) for a single dose of 1,0 ml with or without injection syringe (polypropylene with polyethylene plunger) with or without reconstitution needle and with or without needle for IM injection.

Holder of Certificate of Registration

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