

RABIPUR(R)

(Rab-ee-per)

Inactivated Rabies Virus Vaccine

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about RABIPUR (Inactivated Rabies Virus Vaccine).

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines, including vaccines, have risks and benefits. Your doctor has weighed the risks of you or your child having RABIPUR against the benefits they expect it will have.

If you have any concerns about this vaccine, ask your doctor, nurse or pharmacist.

Keep this leaflet.

You may need to read it again.

What RABIPUR is used for

RABIPUR is a vaccine used to help prevent rabies infection in people who either

- * have been, or
- * are at risk of being bitten, licked or scratched by an animal infected with rabies virus.

Rabies is a very serious infection. The rabies virus attacks the nerves and the brain. Rabies infection can be fatal if not treated as early as possible.

How it works

RABIPUR works by causing your body to protect itself against rabies. The body makes substances that fight the rabies virus. They are called antibodies and circulate in the blood. If the rabies virus gets into someone who has been vaccinated against rabies, the antibodies kill the virus before it can cause damage.

After vaccination your body takes several weeks to develop enough antibodies to successfully fight rabies.

For vaccination against rabies you need a course of 3 to 5 injections.

After this course, most people produce enough antibodies against rabies. However, as with all vaccines, 100% protection cannot be guaranteed.

Further booster injections of rabies vaccine may be needed every few years to ensure enough antibodies are present.

The vaccine will not give you or your child rabies.

The chance of a severe reaction from RABIPUR is very small, but the risks from not being vaccinated against rabies may be very serious.

Before you are given RABIPUR

When you or your child must not be given RABIPUR

Do NOT have RABIPUR if you have :

- * **an allergy to RABIPUR or any of the ingredients listed at the end of this leaflet**
- * **a severe allergy to chicken eggs.**

However, untreated rabies infection can be fatal. Therefore, even if you may be allergic to an ingredient of this vaccine and you have been bitten or scratched by an animal which has/is thought to have rabies, it is essential to have the rabies vaccine. Your doctor will be able to manage any allergic reaction you may have.

- * You or your child is suffering from any illness or has a fever
- * **Do not have RABIPUR after the expiry date printed on the pack.**
- * **Do not have RABIPUR if the packaging is torn or shows signs of tampering.**

If you are not sure whether you or your child should have RABIPUR, talk to your doctor or pharmacist.

Before you or your child are given RABIPUR

Tell your doctor if you have, or have had, any medical conditions, especially the following:

- * **low immunity due to an illness OR treatment with medicines such as corticosteroids,**

cyclosporin or cancer treatment (including radiation therapy);

- * a severe allergy to chicken eggs
- * an allergy to antibiotics, particularly neomycin, chlortetracycline or amphotericin B.

Tell your doctor if you are pregnant or intend to become pregnant.

Your doctor will discuss the possible risks and benefits of having RABIPUR during pregnancy.

Tell your doctor if you are breast-feeding.

Your doctor will discuss the possible risks and benefits of having RABIPUR during breastfeeding.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

RABIPUR and some medicines may interfere with each other. These include:

- * medicines that lower the body's immunity, such as corticosteroids, cyclosporin or other medicines used to treat cancer (including radiation therapy)

These medicines may be affected by RABIPUR or may affect how well it works. You may need different amounts of these medicines, or you may need to take different medicines. Your doctor or pharmacist will advise you.

How RABIPUR is given

A doctor or nurse gives RABIPUR as an injection (usually into muscle in your upper arm).

RABIPUR should not be injected directly into the skin or a vein.

How much is given

Each injection of rabies vaccine is 1.0mL.

Your doctor will decide how many injections of RABIPUR you will need.

When it is given

"Post exposure":

RABIPUR may be given to people after they have been exposed to rabies infection.

The usual course is 4 to 5 injections, given at intervals over 3 or 4 weeks.

"Pre-exposure":

RABIPUR may be given in advance to people at risk of being infected with rabies.

The usual course is 3 injections given at intervals over 3 - 4 weeks.

"Booster Injections":

After two to five years, depending on the circumstances, a booster injection may be needed. Further boosters may be needed every few years.

Your doctor will tell you how many injections you should have and when you should have them.

Follow carefully all your doctor's directions.

If you miss a dose

If you miss a dose, talk to your doctor and arrange another visit as soon as possible.

Overdose

Overdose is most unlikely because your doctor or nurse gives the injections.

If you have any concerns, ask your doctor.

After having RABIPUR

Things you or your child must do

- * **Keep an updated record of your vaccinations.**
- * **Keep follow-up appointments with your doctor or clinic.**

It is important to have your follow-up doses of RABIPUR, and any blood tests, at the correct intervals. This gives the vaccine the best chance of providing protection against rabies and allows the antibody level to be measured.

Side effects

Tell your doctor or pharmacist as soon as possible if you or your child do not feel well after having RABIPUR.

Ask your doctor or pharmacist to answer any questions you may have.

RABIPUR may have unwanted side effects. All medicines, including vaccines can have side effects. Sometimes they are serious, most of the time they are not. You or your child may need medical treatment if you get some of the side effects.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- * any effects at the injection site such as redness, swelling or pain
- * headache
- * fever
- * tiredness
- * generally feeling unwell
- * flu-like symptoms
- * chills
- * increased sweating
- * swollen glands in the neck or armpit
- * muscle ache, weakness, joint pain
- * nausea or vomiting
- * stomach cramps or pain

- * rash

These are common side effects of RABIPUR. Mostly these are mild and short-lived.

Tell your doctor immediately if you notice any of the following:

- * fast or irregular heartbeat or hot flushes
- * problems with vision
- * tingling or numbness of the hands or feet
- * dizziness or light-headedness
- * weakness that restricts movement
- * inability to move or loss of feeling in some parts of the body

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- * signs of allergy, such as itchy pink rash, itchy swellings on the skin (also called hives or nettle rash)
- * swelling of the face, lips, tongue or other parts of the body such as limbs
- * difficulty breathing
- * blue discolouration of the tongue or lips
- * headache and high-temperatures associated with hallucinations, confusion, paralysis of part or all of the body, disturbances of behaviour, speech and eye movements, stiff neck and sensitivity to light.

These are very serious side effects. You or your child may need urgent medical attention or hospitalisation.

All of these side effects are very rare.

This is not a complete list of side effects. Tell your doctor or pharmacist if you notice anything related to RABIPUR that makes you or your child feel unwell.

Storing RABIPUR

RABIPUR is usually stored in the doctor's surgery or clinic, or at the pharmacy. However, if you need to store RABIPUR:

- * **Keep it where children cannot reach it.**
- * **Keep RABIPUR in the original pack until it is time for it to be given.**
- * **Keep it in the refrigerator, between 2 degrees C and 8 degrees C. Do not freeze RABIPUR.**

Freezing can lower the effectiveness of the vaccine.

Product description

What RABIPUR looks like

Each pack of RABIPUR contains

- * one vial of vaccine powder
- * one ampoule of sterile water for injections
- * one disposable syringe

Your doctor will inject the sterile water into the vial to make the liquid for your injection. This liquid is clear and colourless.

Ingredients

Vaccine

Active ingredients:

- * Not less than 2.5 International Units of inactivated Rabies virus (Flury LEP strain)

Other ingredients:

- * Trometamol
- * Sodium chloride
- * Disodium edetate
- * Monopotassium glutamate
- * Polygeline
- * Sucrose
- * Possible trace amounts: neomycin, chlortetracycline, amphotericin B

Diluent

- * Water for Injections

The manufacture of this product includes exposure to bovine derived materials. No evidence exists that any case of vCJD (considered to be the human form of bovine spongiform encephalitis) has resulted from the administration of any vaccine product.

Contains no antimicrobial agent. Product is for single use in one patient only. Discard any residue.

Manufacturer

RABIPUR is made by:

Chiron Behring GmbH & Co KG
P.O. Box 16 30
D-35006 Marburg
Germany

Sponsor

RABIPUR is distributed in Australia by:

CSL Limited ABN 99 051 588 348
45 Poplar Road
Parkville Vic 3052
AUSTRALIA

Registration number

AUST R 100582

Date of preparation

July 2005

RABIPUR(R) is a registered trademark of Chiron Behring GmbH & Co KG