

RABIPUR

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your healthcare professional.

1. Why am I or my child being given RABIPUR?

RABIPUR contains the active ingredient rabies virus (inactivated). RABIPUR is 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.

For more information, see Section [1. Why am I or my child being given RABIPUR?](#) in the full CMI.

2. What should I or my child know before being given RABIPUR?

Do not use if you have ever had an allergic reaction to RABIPUR or any of the ingredients listed at the end of the CMI.

Talk to your healthcare professional if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I or my child know before being given RABIPUR?](#) in the full CMI.

3. What if me or my child is taking other medicines?

Some medicines may interfere with RABIPUR and affect how it works.

A list of these medicines is in Section [3. What I or my child is taking other medicines?](#) in the full CMI.

4. How am I or my child given RABIPUR?

- RABIPUR is given as an injection, usually into your upper arm muscle by a healthcare professional.
- Each injection of rabies vaccine is 1.0 mL.

More instructions can be found in Section [4. How am I or my child given RABIPUR?](#) in the full CMI.

5. What should I or my child know about being given RABIPUR?

Things you should do	<ul style="list-style-type: none">• Keep an updated record of your vaccinations.• Keep follow-up appointments with your healthcare professional 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.
Looking after your medicine	<ul style="list-style-type: none">• RABIPUR is usually stored in the doctor's surgery or clinic, or at the pharmacy• If you need to store RABIPUR, keep in the original pack until it is time for it to be given. Keep it in the refrigerator between 2°C and 8°C. Do not freeze RABIPUR.• Keep it where children cannot reach it.

For more information, see Section [5. What should I or my child know about being given RABIPUR?](#) in the full CMI.

6. Are there any side effects?

All medicines, including vaccines, can have side effects. If you do experience any side effects, most of them may be minor and temporary. However, some side effects may need medical attention.

If you notice any signs of allergy (itchy pink rash, itchy swellings on the skin), 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, tell your healthcare professional immediately or go to the Emergency Department at your nearest hospital.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

RABIPUR (Rab-ee-per)

Active ingredient(s): *Inactivated Rabies Virus*

Consumer Medicine Information (CMI)

This leaflet provides important information about using RABIPUR. **You should also speak to your healthcare professional if you would like further information or if you have any concerns or questions about using RABIPUR.**

Where to find information in this leaflet:

- [1. Why am I or my child being given RABIPUR?](#)
- [2. What should I or my child know before being given RABIPUR?](#)
- [3. What if I or my child is taking other medicines?](#)
- [4. How am I or my child given RABIPUR?](#)
- [5. What should I or my child know about being given RABIPUR?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I or my child being given RABIPUR?

RABIPUR contains the active ingredient rabies virus (inactivated).

RABIPUR is 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.

RABIPUR works by encouraging your body to protect itself against rabies. The body makes substances called antibodies that fight the rabies virus.

If the rabies virus gets into someone who has been vaccinated against rabies, the antibodies kill the virus before it can make you sick.

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, RABIPUR may not fully protect all people who are vaccinated.

For people at risk, 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.

2. What should I or my child know before being given RABIPUR?

Warnings

Do not have RABIPUR if:

- you are allergic to RABIPUR, or any of the ingredients listed at the end of this leaflet,
- you have a severe allergy to chicken eggs.
- you have an acute infection or are suffering from any illness or fever. The presence of a minor infection, such as a cold, should not require postponement of the vaccination.

Untreated rabies infection can be fatal. If you/your child is allergic to an ingredient of this vaccine and was bitten or scratched by an animal thought to have rabies, speak to your healthcare professional to discuss different vaccine options. If there is no alternative rabies treatment available, your healthcare professional will discuss the risks of vaccination and rabies virus infection and manage any allergic reaction you may have.

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

Check with your healthcare professional if you:

Have any other medical conditions especially the following:

- low immunity due to an illness OR treatment with medicines such as corticosteroids, ciclosporin or cancer treatment (including radiation therapy).
- a severe allergy to chicken eggs.
- an allergy to antibiotics, particularly neomycin, chlortetracycline or amphotericin B (amphotericin).
- fainting, feeling faint or other stress-related reactions can occur as a response to any needle injection. Tell your healthcare professional if you have experienced this kind of reaction previously.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Tell your healthcare professional if you are pregnant or intend to become pregnant.

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

Talk to your healthcare professional if you are breastfeeding or intend to breastfeed.

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

3. What if I or my child is taking other medicines?

Tell your healthcare professional if you or your child are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with RABIPUR and affect how it works.

These include medicines that lower the body's immunity, such as corticosteroids, ciclosporin or other medicines used to treat cancer (including radiation therapy). You may need different amounts of these medicines, or you may need to take different medicines. Your healthcare professional will advise you.

Check with your healthcare professional if you are not sure about which medicines, vitamins or supplements you are taking and if these affect RABIPUR.

4. How am I or my child given RABIPUR?

How much is given

- Each injection of rabies vaccine is 1.0 mL.
- You will be given a course of 3 to 5 injections, your healthcare professional administering the vaccine will inform you of the vaccination schedule.
- Further booster injections of rabies vaccine may be needed every few years for people at risk. A blood test will be performed to determine if you need a booster injection.

When is RABIPUR given

"Post exposure"

- RABIPUR may be given to people **after** they have been exposed to rabies infection.
- *Vaccinated individuals*
If you have been fully vaccinated against rabies and/or have received boosters, the usual course is 2 injections.
- *Unvaccinated individuals*
If you have not been vaccinated before or have not received a full vaccination, the usual course is 4 to 5 injections, given at intervals over 3 or 4 weeks.
- *Compromised immune system*
The usual course is 5 or 6 injections.

"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 healthcare professional will tell you how many injections you should have and when you should have them. **Follow carefully all your healthcare professional's instructions.**

How is RABIPUR given

- A healthcare professional gives RABIPUR as an injection (usually into muscle in your upper arm).
- RABIPUR should not be injected directly into the skin or a vein.

If you miss a dose

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

If you are given too much RABIPUR

Overdose is most unlikely because your healthcare professional gives the injections. **If you have any concerns, ask your healthcare professional or telephone the Poisons Information Centre (telephone 13 11 26 in Australia or 0800 POISON (0800 764 766) in New Zealand) for advice.**

5. What should I or my child know about being given RABIPUR?

Things you should do

- Keep an updated record of your or your child's 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.

Looking after your medicine

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

- Keep RABIPUR in the original pack until it is time for it to be given.
- Keep it in the refrigerator, between 2°C and 8°C. Do not freeze RABIPUR. Freezing can lower the effectiveness of the vaccine.

Keep it where children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines, including vaccines, can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your healthcare professional if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> 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, groin or armpit Muscle ache, weakness, joint pain Nausea or vomiting Stomach cramps or pain Rash 	<p>Speak to your healthcare professional if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> Fast or irregular heartbeat or hot flushes Problems with vision Tingling or numbness of the hands or feet Dizziness or light-headedness, feeling faint or fainting Weakness that restricts movement Inability to move or loss of feeling in some parts of the body 	<p>Call your healthcare professional straight away, if you notice any of these serious side effects.</p>
<ul style="list-style-type: none"> 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 	<p>Call your healthcare professional straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these very serious side effects.</p>

movements, stiff neck and sensitivity to light.	
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Tell your healthcare professional if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you or your child experience, you can report side effects to the Therapeutic Goods Administration online at <https://www.tga.gov.au/safety/reporting-problems> (Australia) or to Medsafe at <https://pophealth.my.site.com/carmreportnz/s/> (New Zealand). By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your healthcare professional before you decide to stop receiving any of your medicines.

7. Product details

This vaccine is only available with a prescription.

What RABIPUR contains

Vial of vaccine powder

Active ingredient (main ingredient)	<ul style="list-style-type: none"> Not less than 2.5 International Units of inactivated Rabies virus (Flury LEP strain)
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> Trometamol Sodium chloride Disodium edetate Monopotassium glutamate Polygeline Sucrose
Potential allergens	Possible trace amounts: neomycin, chlortetracycline, amphotericin B (amphotericin).

Pre-filled syringe

Ingredient	Water for injections

Do not take this vaccine if you or your child are allergic to any of these ingredients, UNLESS bitten, licked or scratched by an animal suspected of having rabies.

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 preservative. Product is for single use in one patient only. Discard any residue.

What RABIPUR looks like

Each pack of RABIPUR (Aust R 298194) contains:

- one vial of vaccine powder
- one pre-filled syringe of sterile water for injections

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

Who distributes RABIPUR

RABIPUR is sponsored in Australia by:

Seqirus Pty Ltd
ABN: 26 160 735 035
655 Elizabeth Street,
Melbourne,
Victoria 3000, Australia

Telephone: 1800 642 865

www.cslseqirus.com.au

RABIPUR is sponsored in New Zealand by:

Seqirus (NZ) Ltd
PO Box 62 590
Greenlane, Auckland 1546
New Zealand

Telephone: 0800 502 757

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