

PATIENT INFORMATION LEAFLET
FOR RABIES VACCINE CIPLA

SCHEDULING STATUS

S4

RABIES VACCINE CIPLA (2,5 IU Lyophilised powder for reconstitution)

Purified Rabies Antigen

(Rabies virus Pitman-Moore strain 3218- VERO)

Contains Sugar: sucrose 40 mg

Read all of this leaflet carefully before you are given RABIES VACCINE CIPLA

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

What is in this leaflet

1. What is RABIES VACCINE CIPLA and what is used for:
2. What you need to know before you are administered RABIES VACCINE CIPLA.
3. How to use RABIES VACCINE CIPLA.
4. Possible side effects
5. How to store RABIES VACCINE CIPLA
6. Contents of the pack and other information.

1. What is RABIES VACCINE CIPLA and what it is used for

RABIES VACCINE CIPLA is a sterile, purified rabies vaccine injection. It is a freeze-dried powder that is to be reconstituted with a 1 mL diluent.

RABIES VACCINE CIPLA is indicated for the prevention of rabies in adults and children. It can be used before or after exposure to the rabies virus as well as a booster dose.

Pre-exposure prophylaxis

RABIES VACCINE CIPLA is administered in people who are at risk of being exposed to the rabies virus, such as veterinarians, veterinary medicine students, animal keepers, hunters, forestry workers, animal handlers and other people who are at high risk of exposure to rabies.

Post-exposure prophylaxis

RABIES VACCINE CIPLA is administered immediately to people who are suspected to be exposed to the rabies virus.

Table 1: Contact categories

Category	Type of contact	Recommended treatment
I	Touching or feeding animals, licks on the intact skin	No treatment is required, if a reliable case history is obtained.
II	Nibbling of uncovered skin, minor scratches or abrasions without bleeding	Immediate vaccination

III	Single or multiple transdermal bites or scratches, contamination of mucous membrane with saliva from licks, licks on broken skin, exposure to bats	Immediate vaccination and administration of immunoglobulin
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2. What you need to know before you are administered RABIES VACCINE CIPLA.

Do not take RABIES VACCINE CIPLA

- If you are hypersensitive (allergic) to rabies virus vaccine or any of the other ingredients of RABIES VACCINE CIPLA (listed in **section 6**).
- If you are hypersensitive (allergic) to neomycin (an antibiotic used for bacterial infections).
- If you have a fever or acute (lasting for a short period) illness.

Warnings and precautions

Tell your doctor or health care provider before being given RABIES VACCINE CIPLA:

- If you have been receiving long term corticosteroids (steroid hormones used to treat inflammation) or other immunosuppressive therapy (medicines lowering the body's ability to fight off infections and diseases).
- If you have been receiving chloroquine for malaria treatment or prophylaxis (treatment given to prevent disease).
- If you have a condition affecting the body's immune system and its ability to fight infections and other diseases.
- If you have received an immunoglobulin (antibody) injection.

If any of these applies to you, tell your doctor or nurse before you are given RABIES VACCINE CIPLA.

Tell your doctor or health care provider straight away if you develop any of the following symptoms before being given the injection:

- Fever.
- Any acute illness.
- Neomycin hypersensitivity (allergic) reaction.

Children and adolescents

The vaccine should always be administered intramuscularly (injection in the muscle) in the deltoid area (shoulder muscle) in adults and children under or 2 years old.

In children older than 2 years, the vaccine should be administered in the front and side muscle of the thigh. RABIES VACCINE CIPLA should not be injected in the gluteal (buttocks) area.

Other medicines and RABIES VACCINE CIPLA

Always tell your health care provider if you are taking any other medicine.

It is particularly important that you mention the following:

- Corticosteroids (steroid hormones used to treat inflammation).
- Chloroquine (medication used to treat malaria).
- Immunosuppressive treatment (medicines lowering the body's ability to fight off infections and diseases).
- Immunoglobulins (antibodies).

Pregnancy, breastfeeding and fertility

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 for advice before taking this medicine.

Pregnancy

RABIES VACCINE CIPLA has not been tested in pregnant women, therefore, the administration of this vaccine is not recommended during pregnancy.

Breast feeding

Release of RABIES VACCINE CIPLA in milk has not been established, therefore, caution should be taken when this vaccine is given to a breast feeding mother.

Driving and using machines

It is not always possible to predict to what extent RABIES VACCINE CIPLA may interfere with the daily activities of a patient. Patients should ensure that they do not engage in driving or operating machinery until they are aware of the measure to which RABIES VACCINE CIPLA affects them.

RABIES VACCINE CIPLA contains sugar in the form of sucrose 40 mg.

Tell your doctor or healthcare professional if you are allergic or intolerant to sucrose so that alternate therapy may be recommended.

3. How to take RABIES VACCINE CIPLA

You will not be expected to give yourself RABIES VACCINE CIPLA. It will be given to you by your doctor or by the person qualified to do so.

Your doctor will tell you how long your treatment with RABIES VACCINE CIPLA will last.

The usual dose for *pre-exposure prophylaxis* (given before exposure to prevent disease) is as follows:

Route	Dose	Number of Doses	Schedule
Intramuscular (injection in the muscle)	1 mL	3	Day 0, 7 and 21 or 28
Intradermal (injection in the skin)	0,1 mL	3	Day 0, 7 and 21 or 28

A booster injection is recommended in people whose employment puts them at risk of exposure.

Antibody testing should be done every 6 months for people who are at risk of exposure to high amounts of rabies virus.

A booster dose should be given to a person if the antibody levels killing the rabies virus in their body are below 0,5 IU/mL.

The usual dose for *post-exposure prophylaxis* (given after exposure to prevent disease) is as follows:

Route	Dose	Number of Doses	Schedule
Intramuscular (injection in the muscle)	1 mL	5	Day 0, 3, 7, 14 and 28
Intradermal (injection in the skin)	0,1 mL + 0,1 mL	4	Day 0, 3, 7 and 28

In order to remove as much of the rabies virus as possible, the wound should be immediately cleansed with soap and washed thoroughly with water, then treat with an alcohol (70 %) or a povidone iodine solution.

The vaccination must be given under medical supervision and should be started as soon as possible after exposure.

If you take more RABIES VACCINE CIPLA you should

Since a health care provider will administer RABIES VACCINE CIPLA, he / she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to use RABIES VACCINE CIPLA

Since a health care provider will administer RABIES VACCINE CIPLA, it is unlikely that the dose will be missed.

4. Possible side effects

RABIES VACCINE CIPLA can have side effects.

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

If any of the following happens, stop taking / using RABIES VACCINE CIPLA and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing.

- Rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to RABIES VACCINE CIPLA. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Common side effects:

- Swollen lymph nodes.
- Skin allergic reactions rash, itching and swelling.
- headache, dizziness, drowsiness.
- Abdominal pain and nausea.
- Muscle pain.
- Joint pain, Chills (shivering).
- Fever, asthenia (decreased muscle strength), pain, induration (hardening of soft body tissue).
- Redness of the skin, swelling, itching and general discomfort.
- Flu-like symptoms.

Rare side effects:

- Swelling under the skin.
- Shortness of breathe.
- Headache, dizziness, drowsiness.
- Diarrhoea.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or nurse. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8> or by e-mail: drugsafetysa@cipla.com or telephone: 080 222 6662. By reporting side effects, you can help provide more information on the safety of RABIES VACCINE CIPLA.

5. How to store RABIES VACCINE CIPLA

Store all medicines out of reach of children.

Store at or between 2 °C to 8 °C.

Do not use after the expiry date stated on the label or vial.

Once reconstituted, the product must preferably be used immediately or within 12 hours.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

Contents of the pack and other information

What RABIES VACCINE CIPLA contains

The active substance is:

Rabies antigen (Rabies virus Pitman-Moore strain 3218)

The other ingredients are:

Sucrose

Glycine

Human Serum Albumin (HSA)

What RABIES VACCINE CIPLA looks like and contents of the pack

RABIES VACCINE CIPLA has a milky white friable mass appearance. It is filled in a 13 mm clear tubular glass vials of 16,5 mm diameter and 40 mm height and 4,0 mL overflow volume. Vials are stoppered with a 13 mm rubber stopper and sealed with 13 mm red coloured flip top aluminium seal.

RABIES VACCINE CIPLA is provided with a single 1,0 mL diluent in an ampoule for reconstitution.

For diluent:

1 mL sterile clear, transparent, OPC, USP type-I ampoule.

One monocarton with a tray containing 1 vaccine vial with 1 diluent ampoule –Sterile water for injection 1 mL, packed together + syringe-needle.

One monocarton with a tray containing 1 vaccine vial +1 diluent ampoule –Sterile water for injection 1 mL, packed together.

Multipack of 5 (5 vaccine vials + 5 diluent ampoules –Sterile water for injection 1 mL, packed together).

Box of 50 vials of Rabies vaccine and Box of 50 ampoules of sterile water for injection 1 mL packed separately.

Holder of Certificate of Registration

CIPLA MEDPRO (PTY) LTD.

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Access to the corresponding Professional Information

To access corresponding Professional Information, scan the QR Code below.

PLACE HOLDER: The QR Code to be generated and included after approval.
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