PATIENT INFORMATION LEAFLET FOR

RABIES MAB CIPLA

SCHEDULING STATUS: **S4**

RABIES MAB CIPLA (100 IU / 2,5 mL, solution for injection)

Rabies Human Monoclonal Antibody (rDNA)

Sugar free

Read all of this leaflet carefully before you start using RABIES MAB CIPLA

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- RABIES MAB CIPLA has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

The proposed PIL submitted in this application will comply with the requirements for translation into another official language

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

RABIES MAB CIPLA is indicated as passive antibody component of post-exposure prophylaxis of rabies infection, when given to individuals with suspected rabies exposure. RABIES MAB CIPLA must always be used in combination with a rabies vaccine as part of the post-exposure prophylaxis, as per recommendations of the World Health Organization (WHO). RABIES MAB CIPLA administration depends on the type of contact with a suspected rabid animal.

Category	Type of contact	Recommended treatment
I	Touching or feeding animals, licks on the intact skin	No treatment is required
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 RABIES MAB CIPLA

For all categories, immediate washing and flushing of all bite wounds and scratches is recommended. If indicated, tetanus prophylaxis should also be given with tetanus toxoid.
Treatment should be started as early as possible after exposure, but in no case should it be denied to exposed persons whatever time interval has elapsed.

2. What you need to know before you take RABIES MAB CIPLA

The proposed PIL submitted in this application will comply with the requirements for translation into another official language

Because of the life-threatening risk due to rabies, there are no contraindications to the administration of RABIES MAB CIPLA.

Do not take RABIES MAB CIPLA if:

- you are allergic to Rabies Human Monoclonal Antibody or to any of the excipients used in the formulation of RABIES MAB CIPLA then appropriate precautions must be taken. Speak to your doctor or pharmacist before taking the vaccine.

Warnings and Precautions

Tell your doctor or health care provider before being given the injection:

Take special care with RABIES MAB CIPLA:

- if anaphylaxis or severe allergic reactions occur, administer appropriate medications e.g. epinephrine (adrenaline) and provide supportive care as required.
- Infiltration of wounds in some anatomical sites (finger tips) must be carried out with care in order to avoid increased pressure in the tissue compartment (compartment syndrome).
- The possibility of allergic reactions in individuals sensitive to components of the product should be evaluated. Epinephrine (adrenaline) Hydrochloride Solution (1:1000) and other appropriate agents should be available for immediate use in case an anaphylactic or acute hypersensitivity reaction occurs as per the current recommendations.
- Special care should be taken to ensure that the product is not injected into a blood vessel.
- Under no circumstances should RABIES MAB CIPLA be administered in the same syringe or at the same site as rabies vaccine.
- A separate sterile needle and syringe must be used for each individual patient to prevent the transmission of infectious agents. RABIES MAB CIPLA must not be administered

intravenously. The product must be administered intramuscularly. As with all preparations given intramuscularly, bleeding complications may be encountered in patients with bleeding disorders.

- The recommended dose of RABIES MAB CIPLA should not be exceeded since a higher dose could interfere with the immune response to rabies vaccine.

Children

Because of the life-threatening risk due to rabies, the use of rabies post-exposure prophylaxis is not contraindicated in children under 5 years.

Other medicines and RABIES MAB CIPLA

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.

No drug-drug interaction studies in humans have been conducted with RABIES MAB CIPLA. Repeated doses of RABIES MAB CIPLA should not be administered once the vaccination course has been started as the same may interfere with the immune response of the vaccine.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking RABIES MAB CIPLA**.**

Pregnancy

Because of the life-threatening risk due to rabies, pregnancy and lactation is not a contraindication to rabies post-exposure prophylaxis.

The proposed PIL submitted in this application will comply with the requirements for translation into another official language

It is not known whether RABIES MAB CIPLA can cause fetal harm when administered to a pregnant woman.

Breastfeeding

It is not known whether RABIES MAB CIPLA is secreted in breast milk.

Fertility

Animal reproduction studies have not been conducted with RABIES MAB CIPLA. It is not known whether RABIES MAB CIPLA can affect reproductive capacity.

Driving and using machines

Effect of RABIES MAB CIPLA on ability to drive and use machines is not known.

RABIES MAB CIPLA contains sodium

RABIES MAB CIPLA contains less than 1 mmol sodium (23 mg) per unit volume, that is to say essentially ‘sodium-free”.

3. How to take RABIES MAB CIPLA

You will not be expected to give yourself RABIES MAB CIPLA. It will be given to you by a person who is qualified to do so.

RABIES MAB CIPLA vial should be inspected visually for extraneous particulate matter and/or discoloration before administration. If these conditions exist, it should not be used.

The proposed PIL submitted in this application will comply with the requirements for translation into another official language

RABIES MAB CIPLA is given as a single dose of 3,33 IU/kg body weight at the time of first rabies vaccine dose, as soon as possible after exposure. It is injected around and in the area of the wound. Any remaining volume is injected intramuscularly at a site distant from vaccine administration.

RABIES MAB CIPLA should never be administered in the same syringe or into the same anatomical site as rabies vaccine. DO NOT INJECT INTO THE VEINS.

If you take more RABIES MAB CIPLA than you should

Since a health care provider will administer RABIES MAB 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 MAB CIPLA

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

4. Possible Side Effects

RABIES MAB CIPLA can have side effects.

Not all side effects reported for RABIES MAB CIPLA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking RABIES MAB CIPLA, please consult your doctor, pharmacist or other healthcare professional for advice.

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

The proposed PIL submitted in this application will comply with the requirements for translation into another official language

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,

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

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Redness and itching or irritation at injection site,
- Headache.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Very common side effects:

- Tiredness (Fatigue)
- Muscle pain (Myalgia)
- Joint pain (Arthralgia)

Common side effects:

- Fever
- Chills
- Nausea

The proposed PIL submitted in this application will comply with the requirements for translation into another official language

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, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website, or to Cipla Medpro (Pty) Ltd. by e-mail: drugsafetysa@cipla.com or telephone: 080 222 6662 (toll free) . By reporting side effects, you can help provide more information on the safety of RABIES MAB CIPLA.

5. How to store RABIES MAB CIPLA

- Store at or between 2 °C to 8 °C.
- DO NOT FREEZE. Product which has been exposed to freezing should not be used. RABIES MAB CIPLA contains no preservatives and unused portions must be discarded immediately. Do not use after expiry date.
- Store all medicines out of reach of children.

6. Contents of the pack and other information

What RABIES MAB CIPLA contains

The active substance is Rabies Human Monoclonal Antibody (rDNA) 100 IU/2,5mL.

The other ingredients are Citrate buffer (citric acid and sodium citrate), sodium chloride (NaCl) and polysorbate-80.

What RABIES MAB CIPLA looks like and contents of the pack

RABIES MAB CIPLA: is a clear, colourless liquid, free from any visible particles.
The proposed PIL submitted in this application will comply with the requirements for translation into another official language

RABIES MAB CIPLA: is presented in a 4 mL, 13 mm clear USP Type 1 tubular glass vials. Vials are stoppered with a 13 mm halobutyl rubber stopper and sealed with 13 mm blue coloured flip off aluminum seal.

pack sizes:

100 IU/2,5 mL (40 IU/mL) vial.

Mono carton – 1 vial packed into a carton

50 vials packed into a box

Not all pack sizes may be marketed.

Holder of Certificate of Registration

CIPLA MEDPRO (PTY) LTD.

Building 9

Parc du Cap

Mispel Street

Bellville

7530

Customer Care: 080 222 6662

This leaflet was revised in

First authorisation: To be allocated.

Latest renewal: Not applicable.

Revision: To be allocated.

Registration number(s)

The proposed PIL submitted in this application will comply with the requirements for translation into another official language

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.

The proposed PIL submitted in this application will comply with the requirements for translation into another official language

UM