PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S2**

HEP B VACCINE ADULT CIPLA

Suspension for Injection

(20 mcg Purified Hepatitis B surface antigen per 1,0 mL)

Sugar free

HEP B VACCINE PAED CIPLA

Suspension for Injection

(10 mcg Purified Hepatitis-B surface antigen per 0,5 mL)

Sugar free

Read all of this leaflet carefully because it contains important information for you

- HEP B VACCINE CIPLA is available without a doctor's prescription for you to prevent hepatitis B infection. Nevertheless, you still need to use HEP B VACCINE CIPLA carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share HEP B VACCINE CIPLA with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.

What is in this leaflet:

1. What is HEP B VACCINE CIPLA and what it is used for
2. What you need to know before you take HEP B VACCINE CIPLA
3. How to take HEP B VACCINE CIPLA
4. Possible side effects

5. How to store HEP B VACCINE CIPLA

6. Contents of the pack and other information

1. What HEP B VACCINE CIPLA is and what it is used for

HEP B VACCINE CIPLA is a vaccine used to prevent hepatitis B infection.

Hepatitis B is an infectious illness of the liver caused by a virus.

Immunisation against hepatitis B is expected in the long term to reduce not only the incidence of this disease, but also its chronic complications such as serious liver damage and in some cases cancer of the liver.

Some people have the hepatitis B virus in their body but cannot get rid of it. They can still infect other people and are known as carriers. The disease is spread by the virus entering the body following contact with body fluids, most often blood, from an infected person. If the mother is a carrier of the virus she can pass the virus to her baby at birth. It is also possible to catch the virus from a carrier through, for example, unprotected sex, shared injection needles or treatment with medical equipment which has not been properly sterilised. The main signs of the illness include headache, fever, sickness and jaundice (yellowing of the skin and eyes) but in some patients there are no signs of illness. HEP B VACCINE CIPLA is a vaccine used to prevent hepatitis B infection. HEP B VACCINE CIPLA is not infectious and cannot make you ill.

When you are given the vaccine it will trigger the body’s immune system to prepare itself to protect against these viruses in the future. HEP B VACCINE CIPLA will not protect you if you have already caught the hepatitis

B virus. HEP B VACCINE CIPLA can only help to protect you against infection with hepatitis B virus.

2. What you need to know before you take HEP B VACCINE CIPLA.

Do not receive HEP B VACCINE CIPLA

- if you are allergic (hypersensitive) to HEP B VACCINE CIPLA or any of the other ingredients in HEP B VACCINE CIPLA
- if you are allergic to any other hepatitis B vaccines
- if you have a high temperature (fever).

Warnings and precautions

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

Special care should be taken with HEP B VACCINE CIPLA

- if you have any allergies
- if you have ever had any health problems after being given a vaccine. Like other vaccines, HEP B VACCINE CIPLA may not be totally effective in protecting you against hepatitis B. A number of factors, such as older age, gender, being overweight, smoking and some long-term problems reduce your immune response to the vaccine. If any of these apply to you, your doctor may decide to give you a blood test or give you an additional dose of HEP B VACCINE CIPLA to make sure you are protected.

Children and adolescents

A dose of 10 mcg of antigen protein in 0,5 mL suspension is recommended for neonates, infants and children and adolescents up to 19 years of age.

Other medicines and HEP B VACCINE CIPLA

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

If you are taking or using other medicines on a regular basis, including complementary or traditional medicines, the use of HEP B VACCINE CIPLA with these medicines may cause undesirable interactions.

It is particularly important that you mention the following:

- if you have been given other vaccines or immunoglobulins
- if you have been given a medicine to suppress or prevent an immune response, including chemotherapy for cancer
- if you have been given corticosteroids to manage certain conditions.

HEP B VACCINE CIPLA can be given at the same time as most other routine vaccines. Your doctor will ensure that the vaccines are injected separately and into different parts of the body. Please consult your doctor, pharmacist, or nurse for advice.

HEP B VACCINE CIPLA with food and drink

HEP B VACCINE CIPLA may be received without regard to food or drink.

Pregnancy and breastfeeding

The safety of HEP B VACCINE CIPLA in pregnancy and breastfeeding has not been established.

If you are pregnant or breastfeeding your baby and you require HEP B VACCINE CIPLA, please consult your doctor, pharmacist, or nurse for advice.

Driving and using machines

HEP B VACCINE CIPLA has no or negligible influence on the ability to drive and use machines.

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

HEP B VACCINE CIPLA contains a small quantity of sodium.

3. How to take HEP B VACCINE CIPLA

Always take HEP B VACCINE CIPLA exactly as described in this leaflet or as your doctor has told you. Check with your doctor if you are not sure.

The immunisation schedule will be discussed with you by a qualified person. You will not be expected to give yourself HEP B VACCINE CIPLA. It will be given to you by a person who is qualified to do so.

Do not share medicines prescribed for you with any other person.

Check with your doctor, pharmacist, or nurse if you are not sure.

The usual dose is:

Newborn babies, infants and younger children:

A dose of 0,5 mL HEP B VACCINE PAED CIPLA suspension for injection is recommended for babies, infants, children, and adolescents up to 19 years of age.

Adults:

A dose of 1,0 mL HEP B VACCINE ADULT CIPLA suspension for injection is recommended for adults aged 20 years and above.

HEP B VACCINE CIPLA will be taken as an injection.

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

If you take more HEP B VACCINE CIPLA than you should

Since a healthcare professional will administer HEP B VACCINE CIPLA, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage. Treatment of adverse effects is symptomatic and supportive.

If you forget to take HEP B VACCINE CIPLA

Since a health care provider will administer HEP B VACCINE CIPLA, it is unlikely that the dose will be missed. Should you forget your doctor's appointment to receive the vaccine, see your doctor, as soon as you remember.

4. Possible side effects

HEP B VACCINE CIPLA can have side effects.

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

Allergic reactions uncommon.

If any of the following happens, after being administered HEP B VACCINE CIPLA 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
- low blood pressure
- difficulty swallowing or breathing • your skin going blue
- loss of consciousness (fainting).
- rash or itching

These signs usually start very soon after the injection has been given to you. These are all very serious side effects. If you have them, you may have had a serious reaction to HEP B VACCINE CIPLA. You may need urgent medical attention or hospitilisation.

Common side effects:

- Soreness
- Injection site pain
- Injection site swelling
- Redness
- Hardening of the skin at the injection site
- Fever
- Feeling unwell
- Flu-like symptoms
- Feeling tired
- Nausea

Less common side effects:

- Vomiting
- Diarrhoea
- Abdominal pain
- Dizziness
- Muscle pain or joint pain and inflammation
- Reactions at the injection site such as a hard lump, rash discoloration
- Rash
- Itching
- Hives
- Cough and cold
- Headache
- Feeling sleepy
- Flushing
- Jaundice
- Body ache

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 to Cipla Medpro (Pty) Ltd. by email: drugsafetysa@cipla.com.

By reporting side effects, you can help provide more information on the safety of HEP B VACCINE CIPLA.

5. How to store HEP B VACCINE CIPLA

- Store all medicines out of the reach of children.
- Store at 2 °C to 8 °C (in a refrigerator). DO NOT FREEZE. Discard if the vaccine has been frozen.
- Keep the container in the outer carton until ready for use.
- Do not use after the expiry date stated on the label.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What HEP B VACCINE CIPLA contains

The active substance is purified hepatitis B surface antigen. The other ingredients are disodium hydrogen phosphate anhydrous, sodium chloride, sodium dihydrogen phosphate dihydrate and water for injection.

What HEP B VACCINE CIPLA looks like and contents of the pack

White turbid suspension in which mineral carrier tends to settle down slowly when stored.

HEP B VACCINE PAED CIPLA

0,5 mL - Single dose type I glass vial packed into single unit cartons, carton of 10 vials or carton of 50 vials.

5 mL - 10 doses type I glass vial packed into carton of 10 vials or carton of 50 vials.

The vial is closed with a grey rubber stopper and an aluminium seal having a blue coloured flip-off cap.

Not all pack sizes may be marketed.

HEP B VACCINE ADULT CIPLA

1 mL - Single dose type I glass vial packed into single unit cartons, carton of 10 vials or carton of 50 vials.

10 mL - 10 doses type I glass vial packed into carton of 25 vials.

The vial is closed with a grey rubber stopper and an aluminium seal having a blue coloured flip-off cap.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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