**PATIENT INFORMATION LEAFLET FOR**

**CIHEXA**

**SCHEDULING STATUS:** **S2**

**CIHEXA Suspension for injection**

Diphtheria, tetanus, *Bordetella pertussis* (whole cell), hepatitis-B (rDNA), poliomyelitis (inactivated) and *Haemophilus influenzae* type b conjugate vaccine (adsorbed)

Sugar free

**Read all of this leaflet carefully before you are given CIHEXA**

- 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.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. (See **section 4**)

**What is in this leaflet**



## 1. What CIHEXA is and what it is used for

CIHEXA belongs to a class of medicine known as vaccines.

CIHEXA is indicated for active immunisation of infants, at or above the age of 6 weeks against diphtheria, tetanus, *Bordetella pertussis*, hepatitis B, poliomyelitis and invasive diseases caused by *Haemophilus influenzae* type b for 3 dose regimen (6, 10 and 14 weeks) for primary vaccination and booster at the age of 12 to 24 months.

## 2. What you need to know before you receive CIHEXA

**CIHEXA should not be administered to you:**

- If you are hypersensitive (allergic) to administration of diphtheria, tetanus, *B. pertussis*, hepatitis B, polio or *Haemophilus influenza* type b or any of the other ingredients of CIHEXA (listed in **section 6**).
- In infants who have experienced an encephalopathy (disease of the brain) occurring within 7 days following previous vaccination with pertussis containing vaccine (whole cell or acellular pertussis vaccines). Pertussis vaccination should be discontinued and the vaccination course should be continued with diphtheria-tetanus, hepatitis B, polio and *Haemophilus influenza* type b vaccines.
- If you have uncontrolled neurologic disorders or uncontrolled epilepsy (seizures). Pertussis vaccine should not be administered to individuals with these conditions until the treatment regimen has been established, the condition has stabilised, and the benefit clearly outweighs the risk.

*Generally, vaccination must be postponed in cases of acute moderate or severe febrile (having or showing symptoms of fever) illness. The presence of a minor infection and/or low-grade fever does not constitute a contraindication.*

**Warnings and precautions**

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

- If your child has had previous exposure to hepatitis B, as vaccination with CIHEXA may not be effective.
- If your child has had previous vaccinations that caused adverse events. If your child has a history of serious or severe reaction within 48 hours of a previous injection with a vaccine containing similar components, administration of CIHEXA must be carefully considered.
- If any of the following events occurred in relation to your child receiving CIHEXA, as a decision to give subsequent doses of vaccine containing the pertussis component will need to be considered:
  - Temperature of 40,5 °C or more within 48 hours of a dose unexplained by another cause.
  - Collapse or shock-like state within 48 hours.
  - Persistent, inconsolable crying lasting 3 hours or more occurring within 48 hours.
  - Convulsions (seizures) with or without fever occurring within three days.
- If your child has any coagulation disorders (conditions that affect blood clotting), including thrombocytopenia (deficiency of platelets in the blood causing bleeding into the tissues, bruising and slow blood clotting after injury), as the injection needs to be given into the muscle.
- If your child has a history of convulsions (seizures) in first-degree family members (siblings and parents). When administered with diphtheria containing vaccines, as contained in CIHEXA, they have an increased risk for neurologic (nerve) events and permanent neurologic damage. Neurologic events may appear within two or three days following vaccination.
- If your child is infected with human immune-deficiency virus (HIV), as your child may not obtain the expected immunological response.

Once vaccinated your child will remain under observation for not less than 30 minutes for monitoring of possible allergic reactions.

**Other medicines and CIHEXA**

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

*Concomitant use with other vaccines*

CIHEXA can be administered together with a pneumococcal polysaccharide conjugate vaccine, measles, mumps, rubella (MMR) containing vaccines, oral polio vaccine, rotavirus vaccines, a meningococcal conjugate vaccine, as it is unlikely to result in an interference with the immune responses. CIHEXA can be given safely and effectively at the same time as BCG, yellow fever vaccines and vitamin A supplementation.

If co-administration with another vaccine is considered, immunisation should be carried out on separate injection sites. CIHEXA must not be mixed with any other vaccines or other parenterally (by injection) administered medicinal products.

As with other intramuscular injections, use with caution in patients on anticoagulant therapy, immunosuppressive therapies, including irradiation, antimetabolites, alkylating agents, cytotoxic medicines and corticosteroids (used in greater than physiologic doses) may reduce the immune response to vaccines. Short-term (< 2 weeks) corticosteroid therapy or intra-articular, bursal or tendon injections with corticosteroids should not be immunosuppressive.

**CIHEXA with food, drink and alcohol**

Not applicable.

**Pregnancy, breastfeeding and fertility**

CIHEXA is not intended for administration to women of child-bearing age, thus human data on use during pregnancy or lactation are not available.

**Driving and using machines**

Not applicable.

## 3. How to receive CIHEXA

CIHEXA should be administered intramuscularly (into the muscle) of the front side of the thigh. You will not be expected to give yourself CIHEXA. 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.

Always receive CIHEXA exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

*Primary vaccination:*

For active immunisation of infants, it is recommended that 3 doses of 0,5 mL to be administered with an interval of at least four weeks between doses starting at six weeks of age.

In countries, where the passing of hepatitis B virus (HBV) from mother to child is common, the first dose of hepatitis B should be given as soon as possible after birth. In this case, CIHEXA can be used to complete the primary series from 6 weeks of age.

*Booster vaccination:*

A booster dose of diphtheria, tetanus, pertussis, *Haemophilus influenza* type b and inactivated polio vaccine should be given preferably during the second year of life (≥ 6 months after last primary dose). Booster doses should be given in accordance with the official recommendations.

Booster dose may be provided to children having received primary vaccinations of CIHEXA or any other diphtheria, tetanus and pertussis containing vaccines and poliomyelitis vaccine (OPV and/or IPV).

**If you receive more CIHEXA than you should**

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

**If you forget to receive CIHEXA**

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

## 4. Possible side effects

CIHEXA can have side effects.

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

If any of the following happens, after receiving CIHEXA tell your doctor immediately or go to the casualty department at your nearest hospital, healthcare centre or clinic:

• 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 CIHEXA. You may need urgent medical attention or hospitalisation.

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:

- Decreased appetite
- Drowsiness (strong desire to sleep)
- Vomiting
- Injection site erythema (redness of the skin)
- Injection site pain
- Injection site swelling
- Unusual crying
- Irritability
- Fever.

Uncommon side effects:

- Rash
- Nodule (growth under the skin at injection site).

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 "**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 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 CIHEXA.

## 5. How to store CIHEXA

- Store between 2 and 8 °C.
- Do not freeze. Discard vaccine if frozen.
- Before use, the vaccine should be shaken in order to obtain a homogenous pinkish to yellowish turbid (cloudy) liquid.
- Keep the vaccine in the outer carton in order to protect from light.
- Do not use this vaccine after the expiry date which is stated on the carton and label.
- The vaccine should be visually inspected for any foreign particulate matter and/or variation of physical aspect prior to administration. In event of either being observed discard the vaccine.
- Store all medicines out of reach of children.
- 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 CIHEXA contains

- The active substances are diphtheria toxoid ≥ 30 IU, tetanus toxoid ≥ 40 IU, *Bordetella pertussis* (whole cell) ≥ 4 IU, hepatitis B surface antigen (rDNA) 15 mcg, inactivated polio

vaccine (Salk strains grown on vero cells), type 1 (Mahoney strain) 40 DU, type 2 (MEF-1 strain) 8 DU, type 3 (Saukett strain) 32 DU, *Haemophilus influenza* type b 10 mcg (conjugate to TT carrier protein 19 to 33 mcg).

- The other ingredients are 0,9 % sodium chloride, 2-phenoxyethanol, aluminium content $Al^{+++}$ (as aluminium phosphate gel), acetic acid and sodium hydroxide.

**What CIHEXA looks like and contents of the pack**

CIHEXA is a suspension for injection, presented in single-dose vial and 10-dose vial (multi dose). It is a pinkish to yellowish turbid liquid in which the mineral carrier (aluminium phosphate adjuvant) tends to settle down slowly on storage.

CIHEXA is packed in:

- Single dose – 2 mL USP Type-I, clear tubular glass vial with rubber stopper and aluminium flip off seal.

50 labelled vials are packed in one cardboard carton.

- Multi dose – 5 mL USP Type-I, clear tubular glass vial with rubber stopper and aluminium flip off seal.

50 labelled vials are packed in one cardboard carton.

Not all pack sizes may be marketed.

**Holder of certificate of registration**

**CIPLA MEDPRO (PTY) LTD.**

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