

## MODULE 1.3.2. PATIENT INFORMATION LEAFLET FOR PCV-10 CIPLA

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

### **PCV-10 CIPLA** Suspension for injection

Pneumococcal polysaccharide conjugate vaccine (10-valent, adsorbed)

Sugar free

#### **Read all of this leaflet carefully before using PCV-10 CIPLA:**

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

#### **What is in this leaflet**

1. What PCV-10 CIPLA is and what it is used for.
2. What you need to know before you use PCV-10 CIPLA.
3. How to use PCV-10 CIPLA.
4. Possible side effects.
5. How to store PCV-10 CIPLA.
6. Contents of the pack and other information.

#### **1. What PCV-10 CIPLA is and what it is used for:**

PCV-10 CIPLA is a vaccine that contains ten polysaccharide serotypes from the bacterium, *Streptococcus pneumoniae*, as antigens or active substances of the medicine.

PCV-10 CIPLA is used to immunise (or in the prevention of) children, aged 6 weeks to 24 months, against diseases caused by *Streptococcus pneumoniae*, which include meningitis (inflammation around the brain), sepsis or bacteraemia (bacteria in the blood stream), pneumonia (lung infection) and ear infections.

PCV-10 CIPLA is used to immunise children aged up to 2 years old against diseases caused by *S. pneumoniae*, which include meningitis (inflammation around the brain), sepsis or bacteraemia (bacteria in the blood stream), pneumonia (lung infection) and ear infections.

## **2. What you need to know before use PCV-10 CIPLA:**

**PCV-10 CIPLA should not be given to you or your child if the following applies to you or your child:**

- Allergic to the active substances or to any of the other ingredients in this medicine (listed in **section 6.1**) or to any other vaccine that contains diphtheria toxoid.

### **Warnings and precautions:**

*Tell your healthcare professional if you have or your child has any of the following conditions:*

- An allergic reaction in the previous vaccination schedule.
- An existing infection, signs include having a fever and a general feeling of being unwell.
- Blood clotting disorders and you or your child are receiving treatment for these disorders, e.g., being prone to bleeding or bruising easily.
- A weak immune system, e.g., if your baby was born prematurely or having HIV disease.
- Breathing problems in premature infants.

- if your child was born very prematurely (at or before 28 weeks of gestation), particularly if your child has a history of breathing problems, as longer gaps than normal between breaths may occur for 2-3 days after vaccination with PCV-10 CIPLA.

**Other medicines and PCV-10 CIPLA:**

Always tell your health care provider if you or your child is receiving any other medicine. This includes all complementary or traditional medicines.

**Driving and using machines:**

Data on “Effects on ability to drive and use machines” are not available.

**3. How to use PCV-10 CIPLA:**

You will not be expected to give your child or yourself PCV-10 CIPLA. It will be given to you by a person who is qualified to do so.

The doctor or nurse will inject the recommended dose of PCV-10 CIPLA preferable into the thigh in infants or upper arm in young children.

*Babies less than 6 months of age: typically, your child should receive an initial course of three injections followed by a booster dose:*

- The first injection may be given from the age of six weeks or two months of age.
- Each injection will be given one month to two months apart.
- A fourth injection (booster) will be given between 9 to 10 months or 12 to 15 months of age.
- You will be told when your child should come back for the next injection.

*Babies who missed PCV-10 CIPLA vaccination in the first 6 months of life will receive PCV-10 CIPLA doses as follows:*

- Catch-up schedule for children aged 7 to 11 months: two primary doses with an interval of at least 1 month between doses. A third or booster dose will be given in the second year of life, at least 2 months after the last primary dose.
- Catch-up schedule for children aged 12 to 24 months: two doses with an interval of at least 2 months between doses.

Since a health care provider will administer PCV-10 CIPLA, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

Since a health care provider will administer PCV-10 CIPLA, it is unlikely that the dose will be missed. If you or your child misses an appointment date, visit the healthcare provider as soon as you remember.

#### **4. Possible side effects:**

PCV-10 CIPLA can have side effects.

Not all side effects reported for PCV-10 CIPLA are included in this leaflet. Should your/ your child's general health worsen or if he/she experiences any untoward effects while taking PCV-10 CIPLA, please consult your health care provider for advice.

*If any of the following happens, tell your doctor immediately and go to the casualty department at your nearest hospital:*

- Anaphylaxis, a life-threatening allergic reaction and may be indicated by swollen face, throat or mouth causing breathing/ eating difficulties, itchy and/or painful skin rash.

*These are all very serious side effects. If you/ your child has them, you/ your child may have had a serious reaction to PCV-10 CIPLA. You/ your child may need urgent medical attention or hospitalisation.*

*Tell your doctor if you notice any of the following:*

*Frequent side effects:*

- Flu-like illness
- Decreased appetite
- Irritability
- Rash
- Fever
- Reddening at the injection site
- Drowsiness
- Pain

*Less frequent side effects:*

- Diarrhoea (runny tummy)

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

### **Reporting of suspected adverse reactions**

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>. By reporting side effects, you can help provide more information on the safety of PCV-10 CIPLA. You may also

report any suspected side effects (to Cipla Medpro (Pty) Ltd) by e-mail:

[drugsafetysa@cipla.com](mailto:drugsafetysa@cipla.com) or telephone: 080 222 6662 (toll free).

#### **5. How to store PCV-10 CIPLA:**

PCV-10 CIPLA must be stored at 2 °C to 8 °C, in the refrigerator.

Shake well.

Do not freeze.

Discard if the vaccine has been frozen. A fine white deposit with clear colourless supernatant may be observed upon storage of the vial. This does not constitute a sign of deterioration.

#### **6. Contents of the pack and other information:**

##### **What PCV-10 CIPLA contains:**

Each 0,5 mL suspension for injection of PCV-10 CIPLA contains the following as active ingredients:

- Pneumococcal polysaccharide serotype 1: 2 mcg;
- Pneumococcal polysaccharide serotype 5: 2 mcg;
- Pneumococcal polysaccharide serotype 6A: 2 mcg;
- Pneumococcal polysaccharide serotype 6B: 4 mcg;
- Pneumococcal polysaccharide serotype 7F: 2 mcg;
- Pneumococcal polysaccharide serotype 9V: 2 mcg;
- Pneumococcal polysaccharide serotype 14: 2 mcg;
- Pneumococcal polysaccharide serotype 19A: 2 mcg;
- Pneumococcal polysaccharide serotype 19F: 2 mcg; and
- Pneumococcal polysaccharide serotype 23F: 2 mcg.

Serotypes are conjugated to CRM197-diphtheria carrier protein 19 to 48 mcg, adsorbed on aluminium phosphate. Each 0,5 mL dose contains 0,125 mg aluminium.

The inactive ingredients are:

- Aluminium phosphate
- L-Histidine
- Polysorbate-20
- Sodium chloride
- Succinic acid
- Water for Injection

**What PCV-10 CIPLA looks like and contents of the pack:**

PCV-10 CIPLA is a suspension for injection.

PCV-10 CIPLA is a whitish turbid liquid (filled in clear glass vials closed with rubber closure, aluminum seal and a polypropylene flip-off cap) tends to settle down on keeping and is free from foreign particles/floccules.

PCV-10 CIPLA is marketed in a mono-carton pack or packs of 50's in clear or amber, tubular glass vials that are fitted with grey rubber stoppers containing an aluminium seal with polypropylene flip-top cap, that are packed into an outer carton.

**Holder of certificate of registration:**

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**This leaflet was last revised in:**

Not applicable

**Application number:**

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

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