

PATIENT INFORMATION LEAFLET

VASOPRESSIN CIPLA

SCHEDULING STATUS: **S4**

VASOPRESSIN 40 units / 100 mL CIPLA, Solution for injection

VASOPRESSIN 60 units / 100 mL CIPLA, Solution for injection

Vasopressin

Contains sugar: Dextrose anhydrous 50,0 mg/mL

Read all of this leaflet carefully before you are given VASOPRESSIN CIPLA because it contains important information for you.

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

What is in this leaflet:

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

1. What VASOPRESSIN CIPLA is and what it is used for

VASOPRESSIN CIPLA contains vasopressin – a polypeptide hormone. It is an 'antidiuretic' which helps to prevent excess loss of water in your urine and narrows some blood vessels in the body.

VASOPRESSIN CIPLA is indicated to increase blood pressure in adults with vasodilatory shock who continue to have decreased blood pressure despite fluids and catecholamines.

2. What you need to know before you are given VASOPRESSIN CIPLA

Do not receive VASOPRESSIN CIPLA

- if you are allergic (hypersensitive) to vasopressin or any of the other ingredients of VASOPRESSIN CIPLA (listed in **section 6**).
- if you are allergic (hypersensitive) to 8-L-arginine vasopressin.

Warnings and precautions

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

- if you suffer from any diseases or conditions associated with your blood vessels, especially the blood vessels of your heart.
- if you suffer from high blood pressure, heart or kidney disease.
- have ever had an abnormal electrocardiogram (ECG).
- heart rhythm disorders.
- your skin may be monitored for the signs of insufficient blood flow (pallor, cold, pain, abnormal sensations).

Other medicines and VASOPRESSIN CIPLA

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

- Catecholamines such as - dopamine, norepinephrine (noradrenaline), and epinephrine (adrenaline) –may result in an additional increase of blood pressure and heart rate, Your doctor may adjust the dosage of VASOPRESSIN CIPLA while monitoring your blood pressure.
- Nonsteroidal anti-inflammatory drugs (NSAIDs) such as Indomethacin may prolong the effect of VASOPRESSIN CIPLA leading to greater pumping of the blood by the heart and increase in the resistance to blood flow.
- The ganglionic blocking agent tetra-ethyl ammonium increases the effect of VASOPRESSIN CIPLA by 20 % in healthy individuals - Your doctor may adjust the dosage of VASOPRESSIN CIPLA while monitoring your blood pressure.
- Antidepressants such as selective serotonin reuptake inhibitors (SSRIs), tricyclic antidepressants, and other medicines like haloperidol, chlorpropamide, enalapril, methyldopa, pentamidine, vincristine, cyclophosphamide, ifosfamide, felbamate may increase the effects of VASOPRESSIN CIPLA on narrowing blood vessels and increasing blood pressure, as well as controlling urine output. Your doctor may adjust the dosage of VASOPRESSIN CIPLA while monitoring your blood VASOPRESSIN CIPLA.
- Certain medicines like demeclocycline, lithium, foscarnet, clozapine may decrease the effect of VASOPRESSIN CIPLA; your doctor will monitor the same and adjust the dose of VASOPRESSIN CIPLA accordingly.

VASOPRESSIN CIPLA with food, drink, and alcohol

No data available.

Pregnancy, breastfeeding and fertility

VASOPRESSIN CIPLA may produce contraction of uterine muscle that could threaten the continuation of pregnancy.

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 VASOPRESSIN CIPLA.

Driving and using machines

No data available.

It is not always possible to predict to what extent VASOPRESSIN 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 VASOPRESSIN CIPLA affects them.

VASOPRESSIN CIPLA contains dextrose.

VASOPRESSIN CIPLA contains dextrose anhydrous which may have an effect on the control of your blood sugar if you have diabetes mellitus.

3. How to receive VASOPRESSIN CIPLA

Route of administration - Parenteral Injection

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

If you receive more VASOPRESSIN CIPLA than you should

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

If you forget to take VASOPRESSIN CIPLA

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

4. Possible side effects

VASOPRESSIN CIPLA can have side effects.

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

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

Frequency unknown - frequency cannot be estimated from the available data.

- Decreased platelets, bleeding that is not easily controlled.
- An irregular – increase or decrease in heartbeat, Fainting or nearly fainting, have difficulty breathing, chest pain, feeling dizzy or weak, fatigue & tire easily with activity. (Atrial fibrillation, bradycardia).
- Increased bilirubin levels (if you notice yellow discoloration of eyes or skin, or dark-coloured urine).
- Decreased urinary output, swelling due to fluid retention, nausea, fatigue and shortness of breath (Acute renal insufficiency).
- Nausea, headache, confusion and fatigue (Hyponatremia).
- Ischemic skin lesion (that occur when there is reduced blood to the skin).
- Diabetes insipidus (a rare disorder that causes the body to make too much urine)

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, pharmacist. You can also report side effects to SAHPRA via the 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 VASOPRESSIN CIPLA.

5. How to store VASOPRESSIN CIPLA

Ideal Storage: Store between 2 °C and 8 °C (36 °F and 46 °F). Do not freeze.

Shelf life of the product is 24 months when stored at 2 to 8°C from the date of manufacturing.

Vials may be held up to 6 months upon removal from refrigeration to room temperature storage conditions (20 °C to 25 °C [68 °F to 77 °F], USP – United States Pharmacopeia Controlled Room Temperature), anytime within the labelled shelf life. Once removed from refrigeration, unopened vial should be marked to indicate the revised 6-months expiration date. If the manufacturer's original expiration date is shorter than the revised expiration date, then the shorter date must be used. Do not use VASOPRESSIN CIPLA, beyond the manufacturer's expiration date stamped on the vial.

The storage conditions and expiration periods are summarized in the following table.

Pack	Unopened Refrigerated 2°C to 8°C (36°F to 46°F)	Unopened Room Temperature 20°C to 25°C (68°F to 77°F) Do not store above 25°C (77°F)	Opened (After First Puncture)
100 mL Vial	Until manufacturer expiration date	6 months or until manufacturer expiration date, whichever is earlier	Not applicable

Do not use after the expiry date stated on the packaging.

6. Contents of the pack and other information

What VASOPRESSIN CIPLA contains

The active substance in VASOPRESSIN CIPLA is Vasopressin.

VASOPRESSIN 40 units / 100 mL CIPLA contains:

40 units of vasopressin per 100 mL (0,4 international units vasopressin per mL)

VASOPRESSIN 60 units / 100 mL CIPLA contains:

60 units of vasopressin per 100 mL (0,6 international units vasopressin per mL)

The other ingredients are dextrose anhydrous, succinic acid, sodium succinate hexahydrate water for injection, sodium hydroxide (for pH-adjustment) and hydrochloric acid (for pH-adjustment).

What VASOPRESSIN CIPLA looks like and contents of the pack

VASOPRESSIN CIPLA is clear colourless solution free from visible particles filled in 100 mL glass vial, sealed with laminated rubber, stopper and aluminium flip-off seal.

VASOPRESSIN CIPLA is available in 100 mL Din Exim Flint Moulded glass vial with 32 mm rubber stopper and 32 mm aluminium flip off seal 12 bridges (White) both side colourless lacquer. 10 such vials are packed in a carton. Not all pack sizes may be marketed.

Holder of Certificate of Registration**CIPLA MEDPRO (PTY) LTD.**

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VASOPRESSIN CIPLA 60 units / 100 mL: 57/7.2/0403.401

To access corresponding translated Patient Information Leaflet, scan the QR Code below.

PLACE HOLDER:

The QR Code to
be generated and
included after
approval.