

**PATIENT INFORMATION LEAFLET****SCHEDULING STATUS****S4****PHENPRESSOR 10 mg/ml Solution for injection****Phenylephrine hydrochloride****Sugar free**

**Read all of this leaflet carefully before you receive PHENPRESSOR 10 mg/ml**

- 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 PHENPRESSOR 10 mg/ml is and what it is used for
2. What you need to know before you receive PHENPRESSOR 10 mg/ml
3. How to receive PHENPRESSOR 10 mg/ml
4. Possible side effects
5. How to store PHENPRESSOR 10 mg/ml
6. Contents of the pack and other information

**1. What PHENPRESSOR 10 mg/ml is and what it is used for**

The active ingredient in PHENPRESSOR 10 mg/ml is phenylephrine hydrochloride.

Phenylephrine belongs to a group of medicines called anti-hypotensive medicines. PHENPRESSOR 10 mg/ml is used in adults to relieve low blood pressure which may occur during an operation or after an injury.

## **2. What you need to know before you receive PHENPRESSOR 10 mg/ml**

### **PHENPRESSOR 10 mg/ml should not be administered to you:**

- if you are hypersensitive (allergic) to phenylephrine hydrochloride or any of the other ingredients of PHENPRESSOR 10 mg/ml (listed in section 6).
- if you are taking a group of medicines called monoamine oxidase inhibitors (MAOIs) or have stopped taking them within the last 14 days.
- if you have severe uncontrolled high blood pressure.
- If you have an overactive thyroid (hyperthyroidism).
- if you have a slow heart rate.
- if you have uncontrolled heart failure.
- if you have prostatic enlargement.
- if you have heart or circulatory problems.

Use in children is not recommended.

### **Warnings and precautions**

Talk to your doctor or nurse before receiving PHENPRESSOR 10 mg/ml:

- if you have heart conditions such as the following: ischaemic heart disease, dysrhythmia, heart failure, angina pectoris, occlusive vascular disease, high blood pressure or aneurysms.
- if you have diabetes mellitus, diabetic autonomic neuropathy (a complication of diabetes mellitus).
- if you have closed angle glaucoma.



- if you have kidney problems.
- if you have autonomic dysfunction.
- if you are allergic to sulfites.

**Other medicines and PHENPRESSOR 10 mg/ml**

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

Do not use PHENPRESSOR 10 mg/ml with:

- Monoamine oxidase (MAO) inhibitors used for depression, (such as selegiline, moclobemide, linezolid, nialamide, pargyline, phenelzine).

The following medicines may affect or be affected by concomitant use:

- Digoxin (medicine used to treat heart problems).
- Imipramine, minalcipram, venlafaxine (medicines used for depression).
- Cyclopropane and halothane (medicines that are inhaled as anaesthetics).
- Atomoxetine (medicine used to treat attention-deficit hyperactivity disorder (ADHD)).
- Clonidine (medicine used to treat high blood pressure)
- Quinidine (medicine used to treat abnormal heart rhythm).
- Doxazosin, labetalol, prazosin (medicines used to treat high blood pressure).
- Haloperidol, phenothiazines (medicines used to treat mental illness).
- Atropine (medicine used for slow heart rate or pesticide poisoning).
- Lithium (medicine used for depression or aggression).
- Ergot alkaloids, such as bromocriptine, lisuride, carbergoline, pergolide dihydroergotamine, ergotamine, methylergometrine, methylsergide (medicines to treat migraine).

**Pregnancy, breastfeeding and fertility**

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 receiving PHENPRESSOR 10 mg/ml.

The safety of PHENPRESSOR 10 mg/ml during pregnancy and breastfeeding has not been established.

**Driving and using machines**

There are no known adverse effects.

It is not always possible to predict to what extent PHENPRESSOR 10mg/ml may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which PHENPRESSOR 10 mg/ml affects you.

**3. How to receive PHENPRESSOR 10 mg/ml**

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

You will not be expected to give yourself PHENPRESSOR 10 mg/ml. It will be given to you by a person who is qualified to do so.

Your doctor will work out the dosage that is correct for you and will adjust this dosage to meet your individual requirement.

If you have the impression that the effect of PHENPRESSOR 10 mg/ml is too strong or too weak, tell your doctor or pharmacist.

**If you receive more PHENPRESSOR 10 mg/ml than you should**

Since your doctor will administer PHENPRESSOR 10 mg/ml, he/ she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage. Symptoms of overdose include headache, feeling sick, high blood pressure, a fast or irregular heartbeat, confusion, hallucinations and fits.

**If you miss a dose of PHENPRESSOR 10 mg/ml**

Since your doctor will administer PHENPRESSOR 10 mg/ml, it is unlikely that the dose will be missed.

**4. Possible side effects**

PHENPRESSOR 10 mg/ml can have side effects.

Not all side effects reported for PHENPRESSOR 10 mg/ml are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving PHENPRESSOR 10 mg/ml, please consult your health care provider for advice.

If any of the following happens, stop receiving PHENPRESSOR 10 mg/ml and 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, 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 reaction to PHENPRESSOR 10 mg/ml. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

*Frequent*

- headache.

*Less frequent*

- numbness or a burning feeling that occurs most often in the extremities, such as the hands, arms, legs, or feet,

- tremor,
- nervousness,
- difficulty sleeping,
- anxiety and confusion,
- angle closure glaucoma (when pressure rises quickly inside the eye),
- shortness of breath,
- enlarged pupils, which may make your vision blurry,
- increased or decreased blood pressure,
- dizziness,
- feeling sick, vomiting,
- tingling and coolness of the skin, sweating,
- muscle weakness,
- difficulty in passing urine.

*Frequency unknown*

- bleeding in the brain,
- fluid on the lungs,
- a drop in blood pressure may occur with dizziness, fainting and flushing,
- changes in heart rate and rhythm, anginal pain, heart block,
- an increase in saliva,
- a feeling of fullness in the head,
- changes in blood sugar levels,
- occasional skin reactions.

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>. By reporting side effects, you can help provide more information on the safety of PHENPRESSOR 10 mg/ml.

**5. How to store PHENPRESSOR 10 mg/ml**

Store all medicines out of reach of children.

- Store at or below 25 °C. Protect from light.
- Do not use after the expiry date stated on the label/ carton

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 PHENPRESSOR 10 mg/ml contains**

- The active substance is phenylephrine hydrochloride. Each 1 ml of PHENPRESSOR 10 mg/ml contains 10 mg of phenylephrine hydrochloride. Sugar free.
- The other ingredients are citric acid monohydrate, hydrochloric acid, sodium chloride, sodium citrate dihydrate, sodium hydroxide, sodium metabisulfite, water for injection.

**What PHENPRESSOR 10 mg/ml looks like and contents of the pack**

A clear colourless solution with a pH range of 3,5 to 5,0.

PHENPRESSOR 10 mg/ml is packed as follows:

- 5 ml USP Type-I Clear glass tubular vial closed with 20 mm grey chlorobutyl rubber stoppers and 20 mm aluminium flip-off seals with blue colour button.
- 10 ml USP Type-I Clear glass tubular vial closed with 20 mm grey chlorobutyl rubber stoppers and 20 mm aluminium flip-off seals with orange colour button.

**Holder of Certificate of Registration**

**Kahma Biotech (Pty) Ltd**

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To be confirmed.