1.5.5.2 CLEAN PROPOSED PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

PHENYLEPHRINE HYDROCHLORIDE INJECTION 10 mg/mL solution for injection

Sugar free

Read all of this leaflet carefully before you start using PHENYLEPHRINE HYDROCHLORIDE INJECTION

- 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.
- PHENYLEPHRINE HYDROCHLORIDE INJECTION has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1.5.5.2 CLEAN PROPOSED PATIENT INFORMATION LEAFLET

1. What PHENYLEPHRINE HYDROCHLORIDE INJECTION is and what it is used for

PHENYLEPHRINE HYDROCHLORIDE INJECTION belongs to a group of medicines called adrenergic- and dopaminergic medicines, which raise blood pressure by constricting blood vessels.

PHENYLEPHRINE HYDROCHLORIDE INJECTION is used to treat low blood pressure, which may be caused by circulatory failure, spinal anaesthesia or certain medicines.

2. What you need to know before you receive PHENYLEPHRINE HYDROCHLORIDE INJECTION

PHENYLEPHRINE HYDROCHLORIDE INJECTION should not be administered to you:

- If you are hypersensitive (allergic) to phenylephrine hydrochloride or any of the other ingredients of PHENYLEPHRINE HYDROCHLORIDE INJECTION (listed in section 6).
- If you are a child.
- If you suffer from high blood pressure.
- If you have an overactive thyroid.
- If you are taking non-selective monoamine oxidase inhibitors (MAOIs) used to treat depression (e.g. iproniazid, nialamide, linezolid, phenelzine), or have taken them in the last 14 days.
- If you have or had heart block (slow or irregular heartbeat) within the last 3 months.
- If you have suffered from a heart attack.
- If you suffer from heart failure.
- If you have seriously impaired coronary circulation (circulation of blood in the blood vessels of the heart muscle).
- If you have bradycardia (slower than normal heart rate).

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Warnings and precautions:

Talk to your doctor before being given PHENYLEPHRINE HYDROCHLORIDE INJECTION if:

- You have any heart problems or disease, including an irregular heartbeat or angina (chest pain).
- You are elderly.
- You have impaired blood flow to the brain (cerebral circulation).
- You have a disease of your blood vessels, such as arteriosclerosis or dilated blood vessels.
- You have a disease causing poor circulation in your hands and feet.
- You suffer from diabetes mellitus.
- You suffer from a nerve (autonomic) dysfunction that regulates your heart rate and blood pressure.
- You suffer from septic shock (a widespread infection causing organ failure and a dangerous drop in blood pressure).
- You have closed-angle glaucoma (increased pressure in the eye).
- You are pregnant or breastfeeding.

Children and adolescents:

PHENYLEPHRINE HYDROCHLORIDE INJECTION is not indicated for use in children.

Other medicines and PHENYLEPHRINE HYDROCHLORIDE INJECTION:

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

Do not use PHENYLEPHRINE HYDROCHLORIDE INJECTION with:

- Certain medicines used to treat depression (e.g. iproniazid, nialamide, linezolid, phenelzine).

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Tell your doctor or nurse if you are taking any of the following medicines:

- Medicines used to treat migraine (e.g. dihydroergotamine, ergotamine, methylergometrine methylsergide).
- Medicines used to treat Parkinson's disease (e.g. bromocriptine, lisuride, cabergoline, pergolide).
- Other medicines used to treat depression (e.g. imipramine, minalcipram, venlafaxine, moclobemide, toloxatone, selegiline, pargyline).
- Linezolid (an antibiotic).
- Medicines used to treat high blood pressure (e.g. guanethidine, reserpine).
- Medicines used to treat heart conditions, including cardiac glycosides, quinidine or digoxin.
- Anaesthetics that are inhaled (e.g. desflurane, enflurane, halothane, isoflurane, methoxyflurane, sevoflurane).
- Medicines known as alpha blockers (used to treat Reynaud's syndrome or tumour of the adrenal gland e.g. doxazosin, labetalol, prazosin, haloperidol, phenothiazines) or beta blockers (used to treat heart conditions or reduce blood pressure).
- Diuretic medicines (sometimes called "water pills") used to treat high blood pressure.
- Medicine used to treat symptoms of a slow heartbeat, reduce salivation and bronchial secretion before surgery or to treat mushroom poisoning and overdose with certain medicines called cholinergic medicines (atropine sulfate).
- Medicine used during labour (oxytocin).
- Granisetron used to prevent nausea and vomiting.
- Doxazosin used to treat high blood pressure or symptoms of an enlarged prostate.
- Buspirone used to treat anxiety.

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Pregnancy and breastfeeding:

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 this medicine.

Pregnancy

The use of PHENYLEPHRINE HYDROCHLORIDE INJECTION in late pregnancy or labour may potentially cause a slow heartbeat and low oxygen levels in your unborn baby. Therefore, the use of PHENYLEPHRINE HYDROCHLORIDE INJECTION is not recommended during pregnancy.

Breastfeeding

PHENYLEPHRINE HYDROCHLORIDE INJECTION can pass into your breast milk and should not be used during breastfeeding. However, if you receive only a single dose during childbirth, breastfeeding is possible.

Driving and using machines:

It is not always possible to predict to what extent PHENYLEPHRINE HYDOCHLORIDE INJECTION 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 PHENYLEPHRINE HYDROCHLORIDE affects you.

3. How PHENYLEPHRINE HYDROCHLORIDE INJECTION will be given

You will not be expected to give yourself PHENYLEPHRINE HYDROCHLORIDE INJECTION. It will be given to you in a hospital or clinic by a person who is qualified to do so.

PHENYLEPHRINE HYDROCHLORIDE INJECTION is given by slow injection or infusion (drip)

into a vein.

Your doctor will tell you how long your treatment with PHENYLEPHRINE HYDROCHLORIDE will last. If you have the impression that the effect of PHENYLEPHRINE HYDROCHLORIDE is too strong or too weak, tell your doctor or pharmacist.

If you are given more PHENYLEPHRINE HYDROCHLORIDE INJECTION than you should:

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

If you forget to receive PHENYLEPHRINE HYDROCHLORIDE INJECTION

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

If you stop receiving PHENYLEPHRINE HYDROCHLORIDE INJECTION

When discontinuing therapy with PHENYLEPHRINE HYDROCHLORIDE INJECTION, the dose should be reduced gradually, since sudden withdrawal of therapy may result in severe low blood pressure.

4. Possible side effects

PHENYLEPHRINE HYDROCHLORIDE INJECTION can have side effects.

Not all side effects reported for PHENYLEPHRINE HYDROCHLORIDE INJECTION are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving PHENYLEPHRINE HYDROCHLORIDE INJECTION, please consult your doctor,

pharmacist or other health care provider for advice.

If any of the following happens, stop receiving PHENYLEPHRINE HYDROCHLORIDE INJECTION and tell your doctor immediately or go to the casulaty 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,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to PHENYLEPHRINE HYDROCHLORIDE. You may need urgent medical attention or hospitalisation.

Tell your doctor or nurse immediately if you have any of the following side effects:

- a change in your heart rate (speeding up slowing down or cessation, palpitations),
- an irregular heart beat (dysrhythmias),
- chest pain or pain due to angina,
- an increase in blood pressure with headache, nausea and vomiting,
- a decrease in blood pressure with dizziness,
- difficulty in passing urine or urine retention,
- tissue damage at the site of the injection,
- losing contact with reality and are unable to think and judge clearly (psychotic states),
- shortness of breath (dyspnoea),
- bleeding in the brain (speech disorder, dizziness, paralysisof one side of the body),
- fluids in the lung (pulmonary oedema).

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These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Less frequent side effects:

- sweating,
- excessive production of saliva,
- a feeling of fullness in the head,
- tingling or coolness of the skin,
- anxiety,
- excessive sensitivity of an organ or body part (excitability),
- restlessness (agitation),
- confusion,
- nervousness,
- difficulty falling or staying asleep (insomnia),
- shaking (tremor),
- burning or prickling of the skin (paraesthesia),
- excessive dilation of the pupils (mydriasis),
- increased pressure in the eye (aggrevation of glaucoma),
- pale colour of the skin (pallor or skin blanching),
- goose flesh (piloerection),
- muscular weakness.

If any of the side effects gets worse or you notice any side effects not listed in this leaflet, please tell your doctor or nurse.

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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: http://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of PHENYLEPHRINE HYDROCHLORIDE INJECTION.

5. How PHENYLEPHRINE HYDROCHLORIDE INJECTION is stored

- Keep all medicines out of the reach of children.
- Store at or below 25 °C.
- Protect from sunlight.
- Store in the original package.
- Do not use PHENYLEPHRINE HYDROCHLORIDE INJECTION after the expiry date which is stated on the carton and ampoule.
- Keep covered in carton until time of use.
- For single use only. Discard unused portion.

6. Contents of the pack and other information

What PHENYLEPHRINE HYDROCHLORIDE INJECTION contains

- The active ingredient is phenylephrine hydrochloride. Each 1 mL ampoule contains 10 mg phenylephrine hydrochloride.
- The other ingredients are hydrochloric acid, nitrogen, sodium hydroxide and water for injection.

What PHENYLEPHRINE HYDROCHLORIDE INJECTION looks like and contents of the pack:

Colourless, sterile, aqueous solution, practically free from extraneous material, for parenteral

administration packed in 5 x 1 ml amber colour, type I glass open ampoules, with snap-off neck packed in a tray and cardboard carton.

Holder of certificate of registration:

Abbott Laboratories S.A. (Pty) Ltd.

Abbott Place

219 Golf Club Terrace

Constantia Kloof

1709

South Africa

This leaflet was last revised in:

Date of registration: 30 August 1976

Date of revision: 05 October 2022

Registration number:

H630 (Act 101 of 1965)

NAME AND ADDRESS OF THE MANUFACTURER OF THE MEDICINE

Alfasigma S.p.A

Via Enrico Fermi, 1

65020 Alanno (PE)

Italy

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Country	Registration number	Category of Distribution
Botswana	B9301910	S2
Namibia	90/3.1/0051	NS1