

2. What you need to know before you are given Phenylephrine 50 µg/mL PS Equity

Phenylephrine 50 µg/mL PS Equity should not be administered to you:

- if you are hypersensitive (allergic) to phenylephrine hydrochloride or any of the other ingredients of Phenylephrine 50 µg/mL PS Equity (listed in section 6);
- if you suffer from high blood pressure, or peripheral vascular disease (poor blood circulation, particularly in the limbs);
- if you are taking a Monoamine Oxidase inhibitor (MAO) (or within 2 weeks of their withdrawal), that is used to treat depression (such as iproniazide, nialamide);
- if you suffer from severe overactive thyroid gland (hyperthyroidism);
- if you have one of the following serious heart conditions: heart-block, uncontrolled heart failure, poor blood circulation in the heart;
- if you have a very slow heartbeat (called bradycardia);
- if you are taking medicines causing narrowing of the blood vessels (ephedrine, pseudoephedrine, methylphenidate);
- if you are taking medicines given by mouth or via the nose causing narrowing of the blood vessels (etilefrine, midodrine, naphazoline, oxymetazoline, synephrine, tetryzoline, tuaminoheptane, tymazoline).

Warnings and precautions

Tell your doctor or healthcare provider before being given the injection:

- if you have diabetes;
- if you suffer from arterial hypertension (high blood pressure);
- if you have an overactive thyroid gland (uncontrolled hyperthyroidism);
- if you have blood vessel disease, such as arteriosclerosis (hardening and thickening of the walls of the

blood vessels), or aneurysms;

- if you suffer from heart disease including chronic heart conditions, peripheral vascular insufficiency, heart rhythm disorders, tachycardia (high heart rate), bradycardia (low heart rate), partial heart block, angina pectoris;
- if you have poor blood circulation in the brain, heart, hands or feet;
- if you are elderly;
- if you suffer from closed angle glaucoma (increased pressure in the eye);
- if you suffer from a sulphite allergy.

In patients with serious heart failure, Phenylephrine 50 µg/mL PS Equity may worsen the heart failure as a consequence of blood vessel constriction.

The blood pressure in your arteries will be monitored during treatment. If you have heart disease, additional monitoring of vital functions will be performed.

Children

Phenylephrine 50 µg/mL PS Equity is not recommended for use in children due to insufficient data on efficacy, safety and dose recommendations.

Other medicines and Phenylephrine 50 µg/mL PS Equity

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

Phenylephrine 50 µg/mL PS Equity is not to be used in combination with (see section 2):

- non-selective monoamine oxidase inhibitors (MAOIs) (iproniazid, nialamide, phenylzine) used to treat depression;

- medicines causing narrowing of the blood vessels (ephedrine, pseudoephedrine, methylphenidate);
- medicines given by mouth or via the nose causing narrowing of the blood vessels (etilefrine, midodrine, naphazoline, oxymetazoline, synephrine, tetryzoline, tuaminoheptane, tymazoline).

Interactions are possible with the following medicines:

- certain antidepressants (iproniazid, nialamide, desipramine, imipramine, nortriptyline, milnacipran, moclobemide, pargyline, selegiline, toloxatone, venlafaxine)
- medicine to treat infection (linezolid);
- certain medicines used to treat migraine (dihydroergotamine, ergotamine, methylergotamine, methylsergide);
- certain medicines used to treat Parkinson's disease (bromocriptine, lisuride, pergolide);
- medicines used to treat high blood pressure (guanethidine, labetalol, prazosin, reserpine and related products);
- medicines used to treat heart failure, certain irregular or abnormal heartbeats and abnormal heart beat (quinidine, digoxin);
- medicine used as an appetite suppressant (sibutramine);
- anaesthetics that are inhaled (desflurane, enflurane, halothane, isoflurane, methoxyflurane, sevoflurane);
- medicine used to inhibit the production of a hormone responsible of lactation (cabergoline);
- medicine used to induce labour (oxytocin);
- medicine used to treat enlarged prostates in men (doxazosin);
- medicines used to treat certain mental conditions (haloperidol, phenothiazine).

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please

Equity Pharmaceuticals (Pty) Ltd
Phenylephrine 50 µg/mL PS Equity, Solution for Injection in
prefilled syringe
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Application no.: 570540

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Approval Date : 17 June 2025

consult your doctor, pharmacist or other healthcare provider for advice before you are given this medicine.

Your healthcare professional will consider and advise regarding the use of
Phenylephrine 50 µg/mL PS Equity during pregnancy and breastfeeding.

Driving and using machines

There is no information of the effects of Phenylephrine 50 µg/mL PS Equity on the ability to drive or operate
a motor vehicle or other heavy machinery.

You should not engage in driving or operating machinery while receiving
Phenylephrine 50 µg/mL PS Equity.

Phenylephrine 50 µg/mL PS Equity contains sodium

Phenylephrine 50 µg/mL PS Equity contains 3,72 mg of sodium per mL (a total of 37,2 mg in a 10 mL
syringe). This is equivalent to 1,9 % of the recommended maximum daily dietary intake of sodium for an
adult, and must be taken into consideration by patients on a salt-restricted diet.

3. How you will be given Phenylephrine 50 µg/mL PS Equity

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

You will not be expected to give yourself Phenylephrine 50 µg/mL PS Equity injection. It will be given to
you by a person who is qualified to do so.

Use in adults

Your doctor will determine the dose to be administered and may repeat or adjust it until the desired effect
is attained.

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Use in patients with impaired renal function

Lower doses of Phenylephrine 50 µg/mL PS Equity may be needed if you have impaired renal function.

Use in patients with impaired liver function

Higher doses of Phenylephrine 50 µg/mL PS Equity may be needed if you have cirrhosis of the liver.

Use in older people

Treatment in older people should be carried out with care.

Use in children

Phenylephrine 50 µg/mL PS Equity is not recommended for use in children due to insufficient data on efficacy, safety and dose recommendations.

Your doctor will tell you how long your treatment with Phenylephrine 50 µg/mL PS Equity will last. If you have the impression that the effect of Phenylephrine 50 µg/mL PS Equity is too strong or too weak, tell your doctor or pharmacist.

If you have been given more Phenylephrine 50 µg/mL PS Equity than you should

Since a healthcare provider will administer Phenylephrine 50 µg/mL PS Equity, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage. You may have the following symptoms: palpitations, cardiac rhythm disorders (tachycardia, cardiac dysrhythmias).

If you forget to use Phenylephrine 50 µg/mL PS Equity

Since a healthcare provider will administer Phenylephrine 50 µg/mL PS Equity, it is unlikely that the dose

will be missed.

4. Possible side effects

Phenylephrine 50 µg/mL PS Equity can have side effects.

Not all side effects reported for Phenylephrine 50 µg/mL PS Equity are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving Phenylephrine 50 µg/mL PS Equity, please consult your healthcare provider for advice.

Some side effects may be serious. Tell your doctor straightaway if you get any of the following:

- chest pain or pain due to the angina,
- an irregular heartbeat,
- feeling the heart pumping in the chest,
- bleeding in the brain (speech disorder, dizziness, paralysis of one side of the body),
- psychosis (loosing contact with reality).

These are all very serious side effects. If you have them, you may have had a serious reaction to Phenylephrine 50 µg/mL PS Equity. You may need urgent medical attention or hospitalisation.

Other side effects include:

Frequent side effect:

- headache.

Less frequent side effects:

- reaction of hypersensitivity (allergy),
- excessive dilation of the pupils,
- increased pressure in the eye (aggravation of glaucoma),

- excitability,
- agitation (restlessness),
- anxiety,
- confusion,
- nervousness,
- insomnia (difficulty falling or staying asleep),
- shaking (tremor),
- feeling of fullness in the head,
- prickling of the skin,
- itching or tingling skin sensation (paraesthesia),
- slow or high heart rate,
- high blood pressure,
- low blood pressure with dizziness,
- difficulty in breathing,
- fluids in the lung,
- nausea,
- vomiting,
- sweating,
- pallor or skin blanching (pale colour of the skin),
- goose bumps,
- tissue damage at the site of the injection,
- muscle weakness,
- difficulty in passing urine or urine retention.

Side effects with unknown frequencies

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- change in the metabolism of glucose (sugar),
- loss of heart function or blood flow to the heart,
- severe pain in the chest,
- fainting,
- flushing,
- cold skin,
- excessive production of saliva,
- excessive sweating.

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of Phenylephrine 50 µg/mL PS Equity.

5. How to store Phenylephrine 50 µg/mL PS Equity

Store all medicines out of reach of children.

Store at or below 30 °C.

Store the syringe in the unopened blister until use. Keep the blister in the outer carton in order to protect from light.

The pre-filled syringe is for single patient only. Discard syringe after use. Do not reuse.

Only clear colourless solution free from particles or precipitates should be used.

Any syringe, even partially used, should be discarded appropriately after use.

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Do not use after the expiry date, which is stated on the carton and ampoule. The expiry date refers to the last day of that month.

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 Phenylephrine 50 µg/mL PS Equity contains

- The active substance is phenylephrine hydrochloride.
- The other ingredients are citric acid monohydrate, sodium citrate, sodium chloride, sodium hydroxide (pH adjuster) and water for injection.

What Phenylephrine 50 µg/mL PS Equity looks like and contents of the pack

A clear, colourless, pyrogen free and sterile solution for injection.

Phenylephrine 50 µg/mL PS Equity is presented in a sterile 10 ml polypropylene pre-filled syringe, ready-to-use, packaged in a unitary transparent blister pack.

The pre-filled syringes are available in box of 10 syringes.

Holder of Certificate of Registration

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This leaflet was last revised in

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Access to the corresponding Professional Information

An electronic copy of the Professional Information (PI) is available on the Equity website
<http://www.equitypharmaceuticals.co.za> or <http://www.sahpra.org.za>.

The following information is intended for healthcare professionals only:

Please prepare the syringe carefully as follows

The pre-filled syringe is for single patient only. Discard syringe after use. Do not reuse.

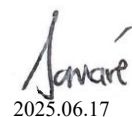
The content of un-opened and un-damaged blister is sterile, and must not be opened until use.

The product should be inspected visually for particles and discoloration prior to
administration. Only clear colourless solution free from particles or precipitates should be used.

The product should not be used if the tamper evident seal on the syringe is broken.

The external surface of syringe is sterile until blister is opened.

When handled using an aseptic method, Phenylephrine 50 µg/mL PS Equity solution for injection in pre-filled syringe can be placed on a sterile field.



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A line drawing of a hand holding a syringe vertically. The plunger is positioned at the 1 mL mark on the scale.

7) Any unused Phenylephrine 50 µg/mL PS Equity or waste material should be disposed of in accordance with local requirements.