

Package leaflet: Information for the patient

Phenylephrine 10 mg/ml Injection phenylephrine hydrochloride

Read all of this leaflet carefully before you start being given this medicine 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.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Phenylephrine Injection is and what it is used for

The name of your medicine is Phenylephrine 10 mg/ml Injection (called Phenylephrine Injection in this leaflet). Its active ingredient is phenylephrine hydrochloride.

Each 1 ml ampoule contains 10 mg of phenylephrine hydrochloride in purified water, Phenylephrine belongs to a group of medicines called anti-hypotensive drugs.

Phenylephrine Injection is used in adults and children to relieve low blood pressure which may occur during an operation or after an injury.

2. What you need to know before you are given Phenylephrine Injection

You should not be given Phenylephrine Injection

- if you are allergic to phenylephrine hydrochloride or any of the other ingredients of this medicine (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 high blood pressure, or an overactive thyroid (hyperthyroidism)
- if you have prostatic enlargement
- if the anterior part (anterior chamber) of your eye is shallow
- if you have a history of acute increase of eye pressure (acute narrow angle glaucoma).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before you are given Phenylephrine Injection

- If you have heart conditions such as the following: ischaemic heart disease, arrhythmia, angina pectoris, occlusive vascular disease, high blood pressure or aneurysms
- If you have diabetes mellitus, diabetic autonomic neuropathy (a complication of diabetes mellitus)

Other medicines and Phenylephrine Injection

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Tell your doctor if you have taken antidepressants (either currently or within the last 14 days)
Tell your doctor if you have taken tablets for heart problems or high blood pressure.

Phenylephrine may interact with some drugs used as general anaesthetics, but your doctor will be fully prepared to deal with this should it occur.

Phenylephrine may interact with a drug used to treat attention-deficit hyperactivity disorder (ADHD) called atomoxetine.

Phenylephrine may also interact with drugs called antimuscarinics (e.g. atropine.)

Lithium (a drug used for depression or aggression) may affect how phenylephrine works.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

The safety of phenylephrine during pregnancy and breast-feeding has not been established.

Driving and using machines

Phenylephrine Injection should not affect your ability to drive. As with all medicines, if you feel unwell you must speak to your doctor or nurse before driving or operating machinery.

Information on sodium content

This medicine contains less than 1 mmol sodium (23 mg) per ml, that is to say essentially 'sodium-free'.

3. How Phenylephrine Injection is given to you

As Phenylephrine Injection is given by injection, the doctor will administer it to you.

Adults: The dose depends on the way it is given, e.g. if injected into a muscle or just under the skin, the recommended dose is 2 to 5 mg. If injected directly into a vein, this is carried out slowly using a more dilute solution of up to 10 mg.

Use in children and adolescents

The recommended dose is 100 micrograms per kilogram of body weight, injected into a muscle or just under the skin.

If you think you have been given more Phenylephrine Injection than you should have

It is unlikely that you will be given too much Phenylephrine Injection; however should an overdose occur the doctor will treat any symptoms that follow. Symptoms of overdose include headache, feeling sick, high blood pressure, a fast or irregular heart beat, confusion, hallucinations and fits..

If you have any further questions on the use of this medicine, ask your doctor or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor or nurse if you experience serious allergic reaction with symptoms such as itching/ rash, swelling of your face, lips or throat or difficulty in breathing/ wheeziness.

Tell your doctor or nurse if you experience other side effects of Phenylephrine Injection which may include:

Not known: frequency cannot be estimated from the available data

- fluid on the lungs and/or bleeding in the brain
- a drop in blood pressure may occur with dizziness, fainting and flushing
- changes in heart rate and rhythm
- racing heart
- anginal pain
- heart block
- difficulty in passing urine, inability to empty bladder completely
- shortness of breath
- enlarged pupils, which may make your vision blurry
- headache
- feeling sick/ vomiting
- tingling and coolness of the skin
- sweating
- an increase in saliva
- a feeling of fullness in the head
- changes in blood sugar levels
- injection site skin reactions
- nervousness
- difficulty sleeping
- angle closure glaucoma (when pressure rises quickly inside the eye)
- increase in blood pressure

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Phenylephrine Injection

KEEP THIS MEDICINE OUT OF THE SIGHT AND REACH OF CHILDREN.

Phenylephrine Injection will be stored either in a refrigerator or at room temperature (2°C – 25°C), protected from light, until it is given to you. The doctor or nurse will check that the expiry date on the label has not passed before you are given the injection.

6. Contents of the pack and other information

What Phenylephrine Injection contains

- The active substance is phenylephrine hydrochloride. Each 1 ml ampoule contains 10 mg of the active substance phenylephrine hydrochloride.
- The other ingredients are sodium hydroxide solution, hydrochloric acid and water for injections.

What Phenylephrine Injection looks like and contents of the pack

Phenylephrine Injection is a clear, colourless or slightly brown solution. It is available in 1 ml glass ampoules, in packs containing either 6 or 10 ampoules. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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This leaflet does not contain the complete information about your medicine. If you have any questions or are not sure about anything, ask your doctor who has access to additional information.

This leaflet was last revised in August 2021.