

**Phenylephrine 100 micrograms/ml
solution for injection/infusion**
(Referred to as “Phenylephrine” in this leaflet)
phenylephrine



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

1. What Phenylephrine is and what it is used for

This medicine belongs to a group of adrenergic and dopaminergic agents.

It is used to treat low blood pressure during anaesthesia.

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

You will not receive Phenylephrine:

- if you are allergic to phenylephrine hydrochloride or any of the other ingredients of this medicine (listed in section 6);
- if you suffer from severe high blood pressure, or peripheral vascular disease (poor blood circulation);
- if you are taking a Monoamine Oxydase 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).

Warnings and precautions

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

- if you are elderly;
- if you are diabetic;
- if you suffer from arterial hypertension;
- if you have an overactive thyroid gland (uncontrolled hyperthyroidism);
- if you have blood vessels disease, such as arteriosclerosis (hardening and thickening of the walls of the blood vessels);
- if you suffer from a particular condition which may lead to a poor blood circulation in the brain;
- if you suffer from an aneurysma;
- if you suffer from heart disease including chronic heart conditions, non severe-peripheral vascular insufficiency, heart rhythm disorders, tachycardia (high heart rate), bradycardia (low heart rate), partial heart block, angina pectoris;
- if you suffer from a closed angle glaucoma (a rare eye disease).

In patients with serious heart failure, phenylephrine may worsen the heart failure as a consequence of blood vessels 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

This medicine is not recommended for use in children due to insufficient data on efficacy, safety and dosage recommendations.

Other medicines and Phenylephrine

Tell your doctor if you are using, have recently used or might use any other medicines, such as :

- certain antidepressants (iproniazid, nialamide, moclobemide, toloxatone, imipramine, milnacipran or venlafaxine);
- medicine used to treat infections (linezolid);
- certain medicines used to treat migraine (dihydroergotamine, ergotamine, methylergometrine, methylsergide);
- certain medicines used to treat Parkinson disease (bromocriptine, lisuride, pergolide);
- medicine used to inhibit the production of a hormone responsible for lactation (cabergoline);
- anaesthetics that are inhaled (desflurane, enflurane, halothane, isoflurane, methoxyflurane, sevoflurane);
- medicine used as an appetite suppressant (sibutramine);
- medicine used to treat high blood pressure (guanethidine);
- medicines used to treat heart failure and certain irregular heartbeats (cardiac glycosides);
- medicine used to treat abnormal heart rhythm (quinidine);
- medicine used during labour (oxytocin).

Pregnancy and breast-feeding

The safety of this medicine during pregnancy and breast-feeding has not been established, but the use of Phenylephrine is possible during pregnancy if necessary.

Use of this medicine during breast-feeding is not recommended. However, in the event of a single administration during childbirth, breast-feeding is possible.

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

Driving and using machines

Talk to your doctor if you want to drive and/or use machines after being given this medicine.

Phenylephrine contains sodium

This medicine contains 78 mg sodium (main component of cooking/table salt) in each vial of 20 mL. This is equivalent to 4% of the recommended maximum daily dietary intake of sodium for an adult.

3. How Phenylephrine is given

The administration will be performed by a healthcare professional with appropriate training and relevant experience, who will decide the correct dosage for you and when and how the injection should be administered.

The recommended doses are:**Use in Adults**

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

Use in patients with impaired renal function (kidneys not functioning well)

Lower doses of phenylephrine may be needed in patients with impaired renal function.

Use in patients with impaired liver function (liver not functioning well)

Higher doses of phenylephrine may be needed in patients with cirrhosis of the liver.

Use in older people

Treatment in older people should be carried out with care.

Use in children

This medicine is not recommended for use in children due to insufficient data on efficacy, safety and dosage recommendations.

If you have been given more Phenylephrine than you should

You may have the following symptoms: palpitations, cardiac rhythm disorders (tachycardia, cardiac arrhythmias), headache, nausea, vomiting, hallucinations, paranoid psychosis.

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

4. Possible side effects

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

Some side effects may be serious (frequencies are not known). Tell your doctor straight away if you get any of the following:

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

Other side effects may include (frequencies are not known):

- reaction of hypersensitivity (allergy),
- excessive dilation of the pupils,
- increased pressure in the eye (aggravation of glaucoma),
- excitability (excessive sensitivity of an organ or body part),
- agitation (restlessness),
- anxiety,
- confusion,
- headache,
- nervousness,
- insomnia (difficulty falling or staying asleep),
- shaking (tremor),
- itching or tingling skin sensation (paraesthesia),
- slow or high heart rate,
- high blood pressure,
- difficulty in breathing,
- fluids in the lung,
- nausea,
- vomiting,
- sweating,
- pallor or skin blanching (pale colour of the skin),
- goose bump,
- tissue damage at the site of the injection,
- muscle weakness,
- difficulty in passing urine or urine retention.

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 HPRC Pharmacovigilance

Website: www.hpra.ie.

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

5. How to store Phenylephrine

Keep this medicine out of the sight and reach of children.

You should not be given this medicine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month. Your doctor or nurse will check this. This medicine does not require any special temperature storage conditions.

Keep the vial in the outer carton in order to protect from light. Do not use this medicine if you notice visible signs of deterioration.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information**What Phenylephrine contains**

- The active substance is phenylephrine hydrochloride.
 - Each ml of solution for injection contains phenylephrine hydrochloride, equivalent to 100 micrograms (0.1 mg) phenylephrine.
 - Each 20 ml vial contains phenylephrine hydrochloride equivalent to 2000 micrograms (2 mg) phenylephrine.
- The other ingredients are sodium chloride, sodium citrate, citric acid monohydrate, sodium hydroxide and water for injections.

What Phenylephrine looks like and contents of the pack

This medicine is a clear colourless solution for injection, in a 20 ml clear type II glass vial closed with a rubber stopper and an aluminium cap.

The vials are available in box of 1 or 10.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Laboratoire AGUETTANT

1, rue Alexander Fleming

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France

This leaflet was last revised in 12/2019.

Detailed information on this medicine is available on the National Agency website.