

Package Leaflet: Information for the User

PHENYLEPHRINE 10MG/ML SOLUTION FOR INJECTION OR INFUSION

(Referred to as Phenylephrine Injection in this leaflet)

Read all of this leaflet carefully before you are given this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or nurse.

In this leaflet:

- 1.What Phenylephrine Injection is and what it is used for
- 2.Before you are given Phenylephrine Injection
- 3.How Phenylephrine Injection will be given
- 4.Possible side effects
- 5.How to store Phenylephrine Injection
- 6.Further information

1. WHAT PHENYLEPHRINE INJECTION IS AND WHAT IT IS USED FOR

Phenylephrine Injection contains phenylephrine hydrochloride, which belongs to a group of medicines known as adrenergic cardiac stimulants. It raises blood pressure by constricting blood vessels.

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

2. BEFORE YOU ARE GIVEN PHENYLEPHRINE INJECTION

You should NOT be given Phenylephrine Injection if any of the following apply to you.

Tell your doctor if:

- you are allergic (hypersensitive) to phenylephrine hydrochloride or any of the other ingredients (listed in section 6)
- you suffer from high blood pressure
- you have an overactive thyroid
- you are taking Monoamine Oxidase Inhibitors (MAOIs) used to treat depression, or have taken them in the last 14 days.
- you suffer from prostatic enlargement

Special care should be taken with Phenylephrine Injection if any of the following apply to you.

Tell your doctor if you have:

- any heart problems or disease, including arrhythmias or angina
- a disease of your blood vessels, such as arteriosclerosis or aneurysms
- diabetes mellitus
- closed-angle glaucoma (increased pressure in the eye)
- you are pregnant or breast-feeding.

Taking other medicines

Please tell your doctor or nurse if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

In particular, tell your doctor or nurse if you are taking any of the following:

- anaesthetics given as a gas that you inhale, such as cyclopropane or halothane
- tricyclic antidepressants
- medicines used to treat heart conditions including cardiac glycosides or quinidine
- medicines used to treat high blood pressure
- medicines known as alpha blockers (used to treat Reynaud's syndrome or tumour of the adrenal gland) or beta blockers (used to treat heart conditions or reduce blood pressure).
- ganisetron used to prevent nausea and vomiting
- clonidine used to treat high blood pressure.
- doxazosin used to treat high blood pressure or symptoms of an enlarged prostate
- buspirone used to treat anxiety.
- atomoxetine used to treat attention-deficit hyperactivity disorder (ADHD)
- lithium carbonate a drug used for depression or aggression.
- monoamine oxidase inhibitors medications prescribed for the treatment of depression.
- atropine or other antimuscarinics used to treat certain types of nerve agent

Pregnancy and breast-feeding

Tell your doctor or nurse if you are pregnant or breast-feeding.

The safety of phenylephrine during pregnancy and breast-feeding has not been established. Giving phenylephrine in late pregnancy or labour may reduce the foetal heart rate and oxygen levels.

3. HOW PHENYLEPHRINE INJECTION WILL BE GIVEN

You will normally be given Phenylephrine Injection in a hospital or clinic. Phenylephrine Injection can be given by an injection under the skin, into a muscle, or diluted and given by slow injection or infusion (drip) into a vein.

Dose for adults, including the elderly:

When given under the skin or into a muscle the usual dose is 2 to 5 mg with further doses of 1 to 10 mg if necessary.

When given as a diluted solution by slow injection into a vein the dose is 100 to 500 micrograms, repeated as necessary after at least 15 minutes.

Alternatively, it may be infused as a diluted solution into a vein (drip), and the dose adjusted according to the response.

Dose for children:

The usual dose is 100 micrograms/kg bodyweight given as an injection under the skin or into a muscle.

If you are given more Phenylephrine Injection than you should

As you will be given Phenylephrine Injection in a hospital or clinic by a qualified healthcare professional, this will be unlikely.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Phenylephrine Injection can cause side effects, although not everybody gets them.

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

- allergic reaction
- a change in your heart rate (speeding up, slowing down or cessation, palpitations)
- an irregular heart beat (arrhythmias)
- chest pain or pain due to angina
- an increase in blood pressure with headache and vomiting, which may cause bleeding in the brain or fluid in the lungs
- a decrease in blood pressure with dizziness
- difficulty in passing urine or urine retention
- fainting or flushing
- difficulty breathing
- nervousness
- excessive dilation of the pupil
- difficulty sleeping
- tissue damage at the site of the injection.
- angle-closure glaucoma (when pressure rises quickly inside the eyes)

Other side effects

- sweating
- excessive production of saliva
- a feeling of fullness in the head
- tingling or coolness of the skin
- altered metabolism including glucose metabolism.

Reporting of side effects

If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: 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 out of the sight and reach of children.

Store below 25°C. Store in the original package.

Do not use after the expiry date, which is stated on the carton and ampoule.

6. FURTHER INFORMATION

What Phenylephrine Injection contains

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

What Phenylephrine Injection looks like and contents of the pack

Phenylephrine Injection is a clear, colourless, sterile solution in a glass ampoule, available in packs of 10 ampoules.

Marketing Authorisation Holder

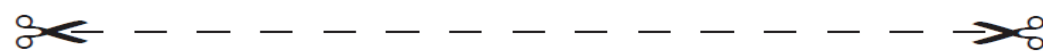
Beacon Pharmaceuticals Limited, The Bower, 4 Roundwood Avenue, Stockley Park, Heathrow, United Kingdom, UB11 1AF.

Manufacturer

Altan Pharmaceuticals, S.A, Polígono Industrial de Bernedo s/n, 01118 Bernedo (Álava), Spain.

This leaflet was last revised in 01/2021

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Package Leaflet: Information for the Healthcare Professional

PHENYLEPHRINE 10MG/ML SOLUTION FOR INJECTION OR INFUSION

The following information is intended for medical or healthcare professionals only:

Qualitative and quantitative composition

Phenylephrine hydrochloride Ph Eur 1.0% w/v. Each 1 ml ampoule contains 10 mg phenylephrine.

Therapeutic indications

For the treatment of hypotensive states, e.g. circulatory failure, during spinal anaesthesia or drug-induced hypotension.

Posology and method of administration

For subcutaneous, intramuscular or slow intravenous injection or by intravenous infusion. Inspect visually for particulate matter and discolouration prior to administration.

Adults:

Phenylephrine injection may be administered subcutaneously or intramuscularly in a dosage of 2 to 5 mg with further doses of 1 to 10 mg if necessary according to response, or in a dose of 100 to 500 micrograms by slow intravenous injection as a 0.1% solution, repeated as necessary after at least 15 minutes.

Alternatively, 10 mg in 500 ml of glucose 5% injection or sodium chloride 0.9% injection may be infused intravenously, initially at a rate of up to 180 micrograms per minute, reduced according to response to 30-60 micrograms per minute.



Children:
100 micrograms/kg bodyweight subcutaneously or intramuscularly.

Elderly:
There is no need for dosage reduction in the elderly.

Pharmacokinetic properties
When injected subcutaneously or intramuscularly, phenylephrine takes 10 to 15 minutes to act. Intravenous injections are effective for up to about 20 minutes, whereas subcutaneous injections are effective for up to one hour and intramuscular injections for up to two hours.

Incompatibilities
Phenylephrine Injection has been stated to be incompatible with alkalis, ferric salts, phenytoin sodium and oxidising agents.

For full prescribing information please refer to the Summary of Product Characteristics



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