Package leaflet: Information for the user
Phenylephrine Hydrochloride 10 mg/ml solution for injection/infusion
(phenylephrine hydrochloride)

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 HYDROCHLORIDE IS AND WHAT IT IS USED FOR

Phenylephrine Hydrochloride 10 mg/ml solution for injection/infusion contains the active substance phenylephrine hydrochloride, which belongs to the group of adrenergic and dopaminergic agents. It raises blood pressure by constricting blood vessels.

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

2. WHAT YOU NEED TO KNOW BEFORE YOU ARE GIVEN PHENYLEPHRINE HYDROCHLORIDE

Do not use Phenylephrine Hydrochloride:
- if you are allergic to phenylephrine hydrochloride or any of the other ingredients of this medicine (listed in section 6)
- if you have severe high blood pressure
- if you have an overactive thyroid
- if you are taking monoamine oxidase inhibitors (MAOIs) used to treat depression or have taken them in the last 14 days
- if you have poor blood circulation (peripheral vascular disease)

Warnings and precautions
Talk to your doctor, pharmacist or nurse before being given Phenylephrine Hydrochloride:
- if you have any heart disease
- if you suffer from heart rhythm disorders
- if you have a disease of the blood vessels, such as arteriosclerosis or aneurysms
- if you have high blood pressure in the arteries (arterial hypertension)
- if you have non-severe peripheral vascular insufficiency

- if you suffer from angina, it can cause pain
- if you have diabetes mellitus
- if you have an increased pressure in the eye (closed-angle glaucoma)
- if you are elderly
- if you suffer from poor blood circulation in the brain or heart
- if you have phaeochromocytoma

In patients with serious heart failure, phenylephrine may worsen the heart failure as a result 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.

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

Phenylephrine Hydrochloride may interact with the following medications:
- monoamine oxidase inhibitors (MAOIs) used for the treatment of depression
- dopaminergic ergot alkaloids (bromocriptine, cabergoline, lisuride, pergolide)
- vasoconstrictor ergot alkaloids (dihydroergotamine, ergotamine, methylergometrine, methysergide)
- tricyclics antidepressants (e.g. imipramine)
- noradrenergic-serotoninergic antidepressants (milnacipran, venlafaxine)
- medicine used to treat infections (linezolid)
- antihypertensives used to treat high blood (guanethidine and related products)
- medicines used to treat heart conditions (cardiac glycosides, quinidine)
- medicine used as an appetite suppressant (sibutramine)
- anaesthetics given as a gas that you inhale (cyclopropane, halothane, desflurane, enflurane, isoflurane, methoxyflurane, sevoflurane)
- medicines used during labour (oxytocic agents)
- alpha-receptor blockers
- beta-receptor blockers

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 being given this medicine.

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 TO USE PHENYLEPHRINE HYDROCHLORIDE

Phenylephrine Hydrochloride must always be administered by a healthcare professional and never by yourself (see section 6). It 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.

The recommended dose is:

Use in adults:

- 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.

Use in patients with renal impairment:

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

Use in patients with hepatic impairment:

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

Use in elderly:

• Treatment in the elderly should be carried out with care.

Use in 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 Hydrochloride than you should

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

Symptoms of overdose include headache, being sick, high blood pressure and reduced heart rate (reflex bradycardia).

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.

The following side effects have been observed, the frequency of which is not known (cannot be estimated from the available data):

- slow heart rate
- fast heart rate
- irregular heart rhythm
- chest pain or pain due to angina

- palpitations
- heart failure
- high blood pressure
- low blood pressure
- redness (flushing)
- headache
- bleeding in the brain
- feeling like you or everything around you is spinning (vertigo)
- fainting
- temporary heaviness of head
- shortness of breath
- fluid in the lungs
- vomiting
- excessive production of saliva

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 HPRA 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 HYDROCHLORIDE

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

Do not use this medicine after the expiry date which is stated on the pack. The expiry date refers to the last day of that month.

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

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Phenylephrine Hydrochloride contains
The active substance is phenylephrine hydrochloride. Each 1 ml ampoule contains 10 mg phenylephrine hydrochloride (8.2 mg phenylephrine base).

The other ingredients are sodium hydroxide, hydrochloric acid, and water for injection.

What Phenylephrine Hydrochloride looks like and contents of the pack
Phenylephrine 10 mg/ml solution for injection/infusion is a clear, colourless, sterile, aqueous solution. It comes in a 1 ml neutral glass ampoule, available in packs containing 10 ampoules.

Marketing Authorisation Holder
Athlone Pharmaceuticals Limited, Connaught House,
1 Burlington Road, Dublin 4, Ireland.

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

Altan Pharmaceuticals, S.A. (CSR plant)
Avda. de la Constitución, 198-199,
Polígono Industrial Monte Boyal,
Casarrubios del Monte, 45950 Toledo, Spain

This leaflet was last revised in September 2023.

Package Leaflet: Information for the Healthcare Professional
Phenylephrine Hydrochloride 10 mg/ml solution for injection/infusion
(phenylephrine hydrochloride)

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 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.

Each 1 ml ampoule contains 10 mg phenylephrine hydrochloride equivalent to 8.2 mg phenylephrine. Dosing of this medicinal product is given in units of phenylephrine hydrochloride rather than in units of phenylephrine which differs from other similar authorised products. Recommended intravenous dosing regimens also vary between formulations. Please take special note of the presentation and concentration of the product and adjust your administration practices accordingly.

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.

Dilution:

Phenylephrine Hydrochloride 10 mg/ml solution for injection/infusion will be administered as an intravenous injection or infusion **after dilution** in glucose 5% w/v solution or sodium chloride 0.9% w/v solution.

To prepare the required concentration, dilute as follows:

Concentration of solution to be administered	Volume of 10 mg/ml solution	Volume of diluent solution
20 micrograms/ml	1 ml	500 ml
50 micrograms/ml	1 ml	200 ml
100 micrograms/ml	1 ml	100 ml
1 mg/ml (0.1% w/v)	1 ml	10 ml