FOR THE INFORMATION OF THE MEDICAL PROFESSION.

Phenylephrine 10 mg/ml Injection

Phenylephrine hydrochloride

Phenylephrine Injection is a sterile solution of Phenylephrine Hydrochloride in purified water.

Phenylephrine is a sympathomimetic agent with mainly direct effects on adrenergic receptors. It has predominantly alpha-adrenergic activity and is without significant stimulating effects on the central nervous system at usual doses. After injection, it produces peripheral vasoconstriction and an increase in arterial pressure. It also produces reflex bradycardia.

Indications

Phenylephrine Injection is indicated in adults and children to treat hypotensive states, for example circulatory failure during spinal anaesthesia, or drug induced hypotension.

Contraindications, Warnings, etc.

Phenylephrine Injection is contraindicated in the presence of severe hypertension and hyperthyroidism. It should not be given to patients being treated with monoamine oxidase inhibitors, nor within two weeks of stopping such treatment. Extreme caution is required in patients with pre-existing cardiovascular disease, such as ischaemic heart disease, arrhythmias and occlusive vascular disease. Anginal pain may be precipitated in patients with angina pectoris. Care is also required in patients with diabetes mellitus or closed angle glaucoma. Avoid in patients with prostatic enlargement.

Interactions

Phenylephrine may interact with cyclopropane, halothane and other halogenated inhalational anaesthetics to induce ventricular fibrillation. There may be an increased risk of arrhythmias with concomitant use of cardiac glycosides, quinidine and tricyclic antidepressants. Phenylephrine, by increasing the blood pressure, may reverse the effect of many antihypertensives. Interactions of phenylephrine with alpha receptor agonists/antagonists and beta receptor blocking drugs may be complex. Caution should be applied when administering atomoxetine concurrently, as there is potential for synergistic pharmacological effects. Severe hypertension may occur following the use of phenylephrine and atropine or other antimuscarinics. The pressor effects of phenylephrine may be slightly reduced by lithium carbonate. The effects of phenylephrine may be potentiated by the use of monoamine oxidase inhibitors or reversible inhibitors of monoamine oxidase.

Use in Pregnancy and Lactation

The safety of phenylephrine during pregnancy has not been established. Due to the vasoconstrictive properties of phenylephrine, the product should be used with caution in patients with a history of pre-eclampsia. Administration in late pregnancy or labour may cause foetal hypoxia and bradycardia.

Breast-feeding

The safety of phenylephrine during lactation has not been established. Excretion of phenylephrine in breast milk appears to be minimal.

Dosage and Administration

Adults:

By subcutaneous or intramuscular injection: 2 to 5 mg, with further doses of 1 to 10 mg if necessary, according to response.

By slow intravenous injection: 100 to 500 micrograms as a 0.1% solution, repeated as necessary after at least 15 minutes.

By intravenous infusion: 10 mg in 500 ml of glucose 5% or sodium chloride 0.9% infused initially at a rate of up to 180 micrograms per minute. This should be reduced to 30 – 60 micrograms per minute according to response.

Elderly: No special dosage reduction necessary.

Paediatric population: 100 micrograms per kilogram of body weight subcutaneously or intramuscularly.

Adverse Effects

- Immune system disorders
- Hypersensitivity
- Metabolism and nutrition disorders
- Metabolic disorders
- Psychiatric disorders
- Nervousness, insomnia
- Nervous system disorders
- Headache, cerebral haemorrhage, paraesthesia
- Eye disorders
- Mydriasis, angle-closure glaucoma
- Cardiac disorders
- Pulmonary oedema, bradycardia, tachycardia, arrhythmia, angina pectoris, palpitations, cardiac arrest
- Vascular disorders
- Hypotension, dizziness, syncope, flushing
- Respiratory, thoracic and mediastinal disorders
- Dyspnoea
- Gastrointestinal disorders
- Vomiting, salivary hypersecretion
- Renal and urinary disorders
- Dysuria, urinary retention
- General disorders and administration site conditions
- Extravasation, infusion site necrosis, hyperhidrosis
- Investigations
- Increased blood pressure, abnormal blood glucose
- Phenylephrine is without significant stimulating effects on the central nervous system at usual doses.

Treatment of Overdosage

Symptoms of overdosage include headache, vomiting, hypertension and reflex bradycardia and other cardiac arrhythmias. In severe cases confusion, hallucinations and seizures may occur. Treatment should consist of symptomatic and supportive measures. Hypertensive effects may be treated with an alpha-blocker such as phentolamine, 5 to 60 mg given intravenously over 10 to 30 minutes, repeated as necessary.

Additional information

Phenylephrine acts within 10 to 15 minutes following subcutaneous or intramuscular injection. Subcutaneous injections are effective for up to around 1 hour and intramuscular injections for up to around 2 hours. Intravenous injections are effective for up to around 20 minutes. Phenylephrine is metabolised in the liver by monoamine oxidase.

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Further information is available on request.

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Package leaflet: Information for the patient

Phenylephrine 10 mg/ml Injection

Phenylephrine hydrochloride

Read all of this leaflet carefully before you start using 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 or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. 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

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 USE PHENYLEPHRINE INJECTION

Do not use Phenylephrine Injection:
- If you are allergic to phenylephrine hydrochloride or any of the other ingredients of this medicine (listed in section 6)
- You are taking a group of medicines called monoamine oxidase inhibitors (MAOIs) or have stopped taking them within the last 14 days
- You have high blood pressure, or an overactive thyroid (hyperthyroidism)
- If you have prostatic enlargement.

Warnings and precautions

Talk to your doctor or pharmacist before using 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) or closed angle glaucoma
- You have inflammation of the liver (hepatitis) or pancreas (pancreatitis)

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.

This medicinal product contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially sodium-free.

3. HOW TO USE PHENYLEPHRINE INJECTION

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 use more Phenylephrine Injection than you should

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.

4. POSSIBLE SIDE EFFECTS

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

Side effects of Phenylephrine Injection may include:

Not known: (frequency cannot be estimated from the available data)
- Allergic reaction symptoms such as itching/ rash, swelling of your face, lips or throat or difficulty in breathing/ wheeziness
- 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
- Anginal pain
- Heart block
- Difficulty in passing urine
- Shortness of breath
- Enlarged pupils, which may make your vision blurry
- Headache
- Feeling sick
- Tingling and coolness of the skin
- Sweating
- An increase in saliva
- A feeling of fullness in the head
- Changes in blood sugar levels
- Occasional skin reactions
- Nervousness
- Difficulty sleeping
- Angle closure glaucoma (when pressure rises quickly inside the eye).

Reporting of side effects

If you get any side effects, talk to your doctor 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, 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

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

What Phenylephrine Injection looks like and the contents of the pack

Phenylephrine Injection is a clear, colourless 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

Amdipharm UK Limited, Capital House, 85 King William Street, London EC4N 7BL, UK

Manufacturer responsible for release

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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.

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