

Package leaflet: information for the user

Ephedrine Hydrochloride 3mg per ml Solution for Injection

Ephedrine Hydrochloride
(Referred to as "Ephedrine Injection" in this leaflet)

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

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

Ephedrine belongs to a group of medicines called sympathomimetics. Sympathomimetic drugs affect the part of your nervous system that works automatically.

Ephedrine Injection is used to relieve low blood pressure during spinal or epidural anaesthesia. It raises blood pressure by temporarily reducing the blood supply to small blood vessels.

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

You should not be given Ephedrine Injection if:

- you are allergic to ephedrine hydrochloride or to any of the other ingredients of this medicine (listed in section 6).
- you are taking another indirect sympathomimetic agent such as phenylpropanolamine, phenylephrine, pseudoephedrine (medicines used to **relieve blocked nose**) or methylphenidate (medicine used to **treat "attention deficit hyperactivity disorder (ADHD)"**),
- you are taking an alpha sympathomimetic agent (medicines used to **treat low blood pressure**),
- you are taking or have taken in the last 14 days a non-selective monoamine oxidase inhibitor (medicines used to **treat depression**).

Warnings and precautions

Talk to your doctor before using Ephedrine Injection if:

- you suffer from diabetes;
- you suffer from heart disease or any other heart conditions, including angina;
- you suffer from weakness in a blood vessel wall leading to a bulge developing (aneurysm);
- you have high blood pressure;
- you have a narrowing and/or blockage of blood vessels (occlusive vascular disorders)
- you have an overactive thyroid gland (hyperthyroidism);
- you know or suspect that you suffer from glaucoma (increased pressure in your eyes) or prostatic hypertrophy (enlarged prostate gland);
- you are about to have an operation which requires that you are given an anaesthetic
- you are currently taking or have taken within the last 14 days any monoamine oxidase inhibitor medicine used to treat depression;

Other medicines and Ephedrine Injection

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

Ephedrine Injection **must not** be used with drugs used to treat severe depression, such as phenelzine or moclobemide, or if you are within 2 weeks of discontinuing them. These drugs are known as monoamine oxidase inhibitors (MAOIs). Other medicines which may interact with Ephedrine Injection are:

- methylphenidate, used to treat "attention deficit hyperactivity disorder (ADHD)";
- indirect stimulators of the sympathetic nervous system such as phenylpropanolamine or pseudoephedrine (medicines used in nasal decongestant), phenylephrine (a medicine used to treat hypotension);
- direct stimulators of alpha receptors of the sympathetic nervous system (oral and/or nasal use) that are used to treat hypotension or nasal congestion, among others;
- anaesthetics that are inhaled, such as halothane;
- medicines used to treat depression;
- Sibutramine, a medicine used as an appetite suppressant
- linezolid, used to treat infections;
- medicines used to treat asthma such as theophylline
- corticosteroids, a type of medicine used to relieve swelling in a variety of different conditions;
- medicines for epilepsy;
- doxapram, medicines used to treat breathing problems;
- oxytocin, a medicine used during labour;
- reserpine and methyl dopa and related medicines, used to treat high blood pressure;
- guanethidine and related medicines, used to treat high blood pressure;
- Ergot alkaloids, a type of medicines used as vasoconstrictors (narrowing blood vessels) or for their dopaminergic action (increasing the dopamine-related activity in the brain).

Pregnancy, breast-feeding and fertility

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.

Laboratory Testing

This medicinal product contains an active ingredient that can induce positive results in anti-doping controls.

Ephedrine Injection contains sodium

This medicinal product contains 2.36 mg (0.102 mmol) of sodium per ml of injection (a total of 23.6 mg or 1.02 mmol sodium in 10 ml syringe). This amount must be taken into consideration by patients on a salt-restricted diet.

3. How Ephedrine Injection is given

This medicine is an injection that will be given to you by your doctor or nurse, into a vein (intravenously). Your doctor will decide the correct dosage for you and when and how the injection should be administered.

The recommended doses are:

Adults, elderly and children over 12 years:

You will be given a slow injection into a vein over several minutes of 3 to 6mg (maximum 9mg) which may be repeated if necessary every 3 to 4 minutes to a maximum of 30mg. Children under 12 years: Not recommended.

Patients with kidney or liver disease:

There are no dose adjustments recommended for patients with kidney or liver disease.

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

If you think you have been given too much Ephedrine Injection

This medicine is given to you by your doctor so it is unlikely you will receive too much. Your doctor has information on how to recognise and treat an overdose. If you are concerned about your treatment, please talk to your doctor. If you have any further questions on the use of this product, ask your doctor or nurse.

Continued overleaf

4. Possible side effects

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

Possible side effects include:

If you get any of the following side effects, stop taking this medicine and seek urgent medical advice straight away:

- difficulty in breathing
- abnormal heart rhythm;
- palpitations, high blood pressure, fast heartbeat, or
- pain over the heart, slow heartbeat, low blood pressure;
- heart failure (cardiac arrest);
- bleeding in the brain;
- build-up of a fluid within the lungs (pulmonary oedema);
- increased pressure in the eye (glaucoma)
- difficulty in passing urine

Other side effects that you may experience while taking this medicine are:

Common (may affect up to 1 in 10 people):

- confusion, feeling worried, depression;
- nervousness, irritability, restlessness, weakness, sleeping problems, headache, sweating
- shortness of breath;
- nausea, vomiting.

Not known (frequency cannot be estimated from the available data):

- affects blood clotting;
- allergy (hypersensitivity);
- changes in your personality or the way you feel/think, fear
- tremor, excessive saliva production
- reduced appetite
- a decrease in blood potassium levels and changes in blood sugar levels

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: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ephedrine Injection

Keep out of the sight and reach of children.

You should not be given this medicine if it has passed the expiry date shown on the carton and ampoule label. Your doctor or nurse will check this. Do not store above 25°C. Keep in the outer carton.

This medicine will only be used for your treatment. Your doctor will dispose of any leftover medicine.

6. Contents of the pack and other Information

What Ephedrine Injection contains.

The **active ingredient** is Ephedrine Hydrochloride 0.3% w/v, equivalent to 3mg ephedrine hydrochloride in 1ml or 30mg ephedrine in 10ml.

The **other ingredients** are Sodium Chloride, Water for Injections and Hydrochloric Acid, Nitrogen PF9

What Ephedrine Injection looks like and contents of the pack.

Ephedrine Injection is a clear, colourless solution for injection. The injection is supplied in 10ml glass ampoules. Each pack contains 10 ampoules.

Marketing Authorisation Holder: Aurum Pharmaceuticals Ltd, T/A Martindale Pharma, Bampton Road, Harold Hill, Romford, RM3 8UG

Manufacturers:

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