

Ephedrine Hydrochloride 30 mg/ml Solution for Injection

ephedrine 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.
- 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.

The name of your medicine is Ephedrine Hydrochloride 30 mg/ml Solution for Injection, which will be referred to as Ephedrine Injection throughout this leaflet.

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 USE EPHEDRINE INJECTION

You should not be given Ephedrine Injection if:

- you are allergic to ephedrine hydrochloride or 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, pharmacist or nurse 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 methyldopa 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).

The following information is intended for healthcare professionals only:

PREPARATION GUIDE:

Ephedrine Hydrochloride 30 mg/ml Solution for Injection

Please refer to the Summary of Product Characteristics for full prescribing and other information.

Therapeutic indications

Reversal of hypotension from spinal or epidural anaesthesia.

Administration

Intravenous use.

Dilution

For single use only.

Ephedrine hydrochloride is compatible with sodium chloride 9 mg/ml (0.9%), Ringer's lactate solution and glucose 50 mg/ml (5%).

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.

3. HOW EPHEDRINE INJECTION IS GIVEN

This medicine is an injection and will be given to you by your doctor. Your doctor will determine the dose you require and how and when the injection will be given.

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.

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;
- 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; changes in blood sugar levels.

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.yellowcard.gov.uk 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 EPHEDRINE INJECTION

This medicinal product does not require any special temperature storage conditions.

Keep the container in the outer carton in order to protect from light.

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 label or carton after EXP. The expiry date refers to the last day of that month.

Do not use this medicine if you notice some visible particles or discolouration in the solution for injection.

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 Ephedrine Injection contains

- The active substance is ephedrine hydrochloride. Each 1 ml of solution for injection contains 30 mg ephedrine hydrochloride.
- The other ingredient is water for injections.

What Ephedrine Injection looks like and contents of the pack

Ephedrine Injection is a clear, colourless and free of visible particles solution for injection supplied in a pack of 5 or 10 clear colourless glass one-point-cut (OPC) ampoules, each containing 1 ml of medicine.

Marketing Authorisation Holder

hameln pharma ltd
Nexus, Gloucester Business Park,
Gloucester, GL3 4AG, United Kingdom

Manufacturer

HBM Pharma s.r.o.
Sklabinská 30
03680 Martin
Slovak Republic

hameln rds s.r.o.
Horná 36
900 01 Modra
Slovak Republic

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

| | |
|-----------------------------------|---|
| Germany | Ephedrin-hameln 30 mg/ml Injektionslösung |
| United Kingdom (Northern Ireland) | Ephedrine Hydrochloride 30 mg/ml Solution for Injection |

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Shelf life

Unopened: 3 years.

Diluted solution:

Chemical and physical in-use stability has been demonstrated for 72 hours at 25°C.

From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8°C, unless dilution has taken place in controlled and validated aseptic conditions.

Special precautions for storage

This medicinal product does not require any special temperature storage conditions.

Keep the container in the outer carton in order to protect from light.