

Package leaflet: Information for the user

Ephedrine Hydrochloride 3 mg/ml solution for injection

ephedrine hydrochloride

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

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

This medicine is a solution for injection in an ampoule used for the treatment of low blood pressure during general and local/regional anaesthesia, whether it be spinal or epidural in adults and adolescents (over 12 years).

This product must be used solely by or under the supervision of the anaesthetist.

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

Do not use 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 are a diabetic;
- you suffer from heart disease or any other heart condition, including angina (chest pain);
- you suffer from weakness in a blood vessel wall leading to a bulge developing (aneurysm);
- you have a 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 if you are using, have recently used or might use any other medicines.

This is especially important for the following medicines:

- 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 low blood pressure);
- direct stimulators of alpha receptors of the sympathetic nervous system (oral and/or nasal use) that are used to treat hypotension (low blood pressure) or nasal congestion, among others;
- medicines used to treat depression;
- 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);
- linezolid, used to treat infections;
- guanethidine and related medicines, used to treat high blood pressure;
- sibutramine, a medicine used as an appetite suppressant;
- anaesthetics that are inhaled such as halothane;
- medicines used to treat asthma such as theophylline;
- corticosteroids, a type of medicines used to relieve swelling in a variety of different conditions;
- medicines for epilepsy;
- doxapram, a medicine used to treat breathing problems;
- oxytocin, a medicine used during labour;
- reserpine and methyl dopa and related medicines, used to treat high blood pressure.
- cardiac glycosides, used to treat congestive heart failure and cardiac arrhythmias;
- quinidine, used to treat heart rhythm disturbances;
- bicarbonate, used to treat metabolic acidosis or for urine alkalinisation;

Pregnancy and breast-feeding

Ephedrine should be avoided or used with caution, and only if necessary, during pregnancy.

Depending on your condition, and following your doctor recommendation, breast-feeding could be suspended for several days following ephedrine administration.

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 medicine contains 33.5 mg sodium (main component of cooking/table salt) in each 10 ml ampoule. This is equivalent to 1.7% of the recommended maximum daily dietary intake of sodium for an adult.

3. How Ephedrine Injection is given

Your doctor or nurse will administer Ephedrine Injection to you into a vein (intravenous). Your doctor will decide the correct dosage for you and when and how the injection should be administered.

The recommended doses are:**Adults and elderly**

You will be given a slow injection of 3 to 6 mg (maximum 9 mg) into a vein, repeated, if necessary, every 3-4 minutes to a maximum of 30 mg.

The total dose must be lower than 150 mg/24 hours.

Use in children and adolescents

- Children under 12 years

This medicine is not recommended for use in children under 12 years old due to insufficient data on efficacy, safety and dosage recommendations.

- Children over 12 years

The posology and method of administration is the same as for adults.

Patients with kidney or liver disease:

There are no dose adjustment 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.

4. Possible side effects

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

The most serious side effects that will require immediate medical attention from your doctor are:

- 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 listed below.

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;
- change in your personality or the way you feel or think, fear;
- tremor, excessive saliva production;
- reduced appetite;
- a decrease in blood potassium levels, changes in blood glucose 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 national reporting system listed in Appendix V. 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.

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

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 ingredient is ephedrine hydrochloride. Each ml of solution for injection contains 3 mg ephedrine hydrochloride. Each 10 ml ampoule contains 30 mg ephedrine hydrochloride.
- The other ingredients are sodium chloride, citric acid monohydrate, sodium citrate and water for injections and may contain hydrochloric acid or sodium hydroxide (for pH adjustments).

What Ephedrine Injection looks like and contents of the pack

Ephedrine Injection is a clear and colourless liquid. It is supplied in a 10 ml polypropylene ampoule.

The polypropylene ampoules are available in boxes of 10.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Laboratoire Aguettant
1 rue Alexander Fleming
69007 Lyon
France

Manufacturer:

Laboratoire Aguettant
Lieu-dit "Chantecaille"
07340 Champagne
France

or

Laboratoire Aguettant
1 rue Alexander Fleming
69007 Lyon
France

This medicinal product is authorised in the Member States of the EEA under the following names:

AT – DE: Ephedrinhydrochlorid Aguettant

BE – LU: Ephedrine HCl Aguettant

NL: Efedrine HCl Aguettant

IE: Ephedrine Hydrochloride

PL: Ephedrinum hydrochloricum Aguettant

ES - PT - IT: Efedrina Aguettant

This leaflet was last revised in 08/2024.

Detailed information on this medicine is available on the HPRA website.

Information intended for healthcare professionals only:

Overdose

In the event of overdose, the occurrence of nausea, vomiting, fever, paranoid psychosis, ventricular and supraventricular arrhythmia, hypertension, respiratory depression, convulsions and coma is observed.

Management

Slow intravenous injection of labetalol 50-200mg may be given with electrocardiograph monitoring for the treatment of supraventricular tachycardia. Marked hypokalaemia ($<2.8\text{mmol.l}^{-1}$) due to compartmental shift of potassium predisposes to cardiac arrhythmia and may be corrected by infusing potassium chloride in addition to propranolol and correcting respiratory alkalosis, when present.

A benzodiazepine and/or a neuroleptic agent may be required to control CNS stimulant effects.

For severe hypertension, parenteral antihypertensive options include intravenous nitrates, calcium channel blockers, sodium nitroprusside, labetalol or phentolamine.