Package leaflet: Information for the user

Ephedrine Hydrochloride 3mg/ml Solution for Injection in Pre-filled Syringe

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.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

This medicine is used for the management of low blood pressure induced by anaesthesia.

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;
- 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 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;
- 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 methyldopa and related medicines, used to treat high blood pressure

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 3.39 mg sodium (main component of cooking/table salt) in each 10 ml pre-filled syringe. 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

Ephedrine Hydrochloride 3 mg/ml solution for Injection in Prefilled Syringe 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
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 Ephedrine Injection

Keep this medicine 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 syringe label. Your doctor or nurse will check this.
Store the blister in the outer carton in order to protect from light.
Any unused product or waste material should be thrown away in accordance with local requirements.

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 prefilled syringe 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 prefilled syringe with a polypropylene tip cap and tamper proof seal, individually packaged in a transparent blister pack.

The prefilled syringes are available in boxes of 1, 5, 10, 12 and 20 syringes.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
LABORATOIRE AGUETTANT
1, rue Alexander Fleming
69007 LYON
France

Manufacturer:
LABORATOIRE AGUETTANT
1, rue Alexander Fleming
69007 LYON
France

or

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This leaflet was last revised in 12/2022.

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