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

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 33.9 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 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 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

LABORATOIRE AGUETTANT
Lieu-dit "Chantecaille"
07340 CHAMPAGNE
France

This leaflet was last revised in 12/2022.
Detailed information on this medicine is available on the MHRA website.

The following information is intended for medical or healthcare professionals only:
This is an extract from the Summary of Product Characteristics to assist in the administration of Ephedrine Injection. When determining appropriateness of use in a particular patient, the prescriber should be familiar with the Summary of Product Characteristics of the product.

Drug name: Ephedrine Hydrochloride 3 mg/ml Solution for injection in Pre-filled Syringe

Safety information
For intravenous injection

Incompatibilities:
In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

Administration:
The pre-filled syringe contains a ready-to-use solution for injection containing 3 mg ephedrine hydrochloride in each ml of solution. Adult Slow intravenous injection of 3 to 6 mg (maximum 9 mg), repeated as needed every 3-4 min to a maximum of 30 mg. A lack of efficacy after 30 mg should lead to reconsideration of the choice of the therapeutic agent. The dose administered for 24 hours must not exceed 150 mg.

Paediatric population
Ephedrine Hydrochloride 3 mg/ml solution for Injection in Prefilled Syringe is generally not recommended for use in children due to insufficient data on efficacy, safety and dosage recommendations.
• Children under 12 years
The safety and efficacy of ephedrine in paediatric patients under 12 years have not been established. No data are available.
• Children over 12 years
The posology and method of administration is the same as for adults.

Patients with renal or hepatic impairment
There are no dose adjustment recommended for patients with renal or hepatic impairment.

Eldery
As for adults.

Method of administration
Ephedrine must be used solely by or under the supervision of the anaesthetist as an injection via intravenous route. For intravenous use.

Overdose:
In the event of overdose, the occurrence of nausea, vomiting, fever, paranoid psychosis, ventricular and supraventricular arrhythmias, hypertension, respiratory depression, convulsions and coma is observed. The lethal dose in humans is approximately 2 g corresponding to blood concentrations of approximately 3.5 to 20 mg/I.
Management
The management of ephedrine overdose with this product may require intensive supportive treatment. Slow intravenous injection of labetalol 50-200 mg may be given with electrocardiograph monitoring for the treatment of supraventricular tachycardia. Marked

hypokalaemia (< 2.8 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.

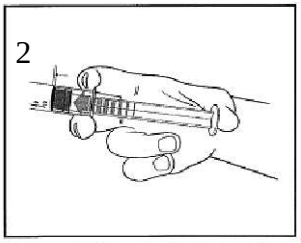
A benzodiazepine and/or a neuroleptic agent may be required to control CNS stimulant effects. For severe hypertension, parenteral antihypertensive options include intravenous nitrates, calcium channel blockers, sodium nitroprusside, labetalol or phentolamine. The choice of antihypertensive drug is dependent on availability, concomitant conditions and the clinical status of the patient.

Instructions for use

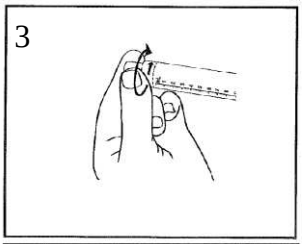
Please prepare the syringe carefully as follows.

The pre-filled syringe is for single patient only.
Discard syringe after use. DO NOT REUSE.
The content of un-opened and un-damaged blister is sterile, and must not be opened until use.
The product should be inspected visually for particles and discoloration prior to administration.
Only clear colourless solution free from particles or precipitates should be used.
The product should not be used if the tamper evident seal on syringe is broken.
The external surface of syringe is sterile until blister is opened.

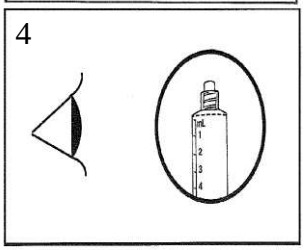
1) Withdraw the pre-filled syringe from the sterile blister.



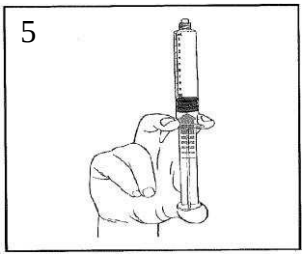
2) Push on the plunger to free the bung.



3) Twist off the end cap to break the seals.



4) Check that the syringe seal has been completely removed. If not, replace the cap and twist again.



5) Expel the air by gently pushing the plunger.

6) Connect the syringe to the IV access. Push the plunger slowly to inject the required volume.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Storage and Shelf life:
Do not use this product after the expiry date which is stated on the carton and syringe label. The expiry date refers to the last day of that month. After opening: the product must be used immediately. Store the blister in the outer carton in order to protect from light.