Package leaflet: Information for the patient

Ephedrine Kabi 3 mg/ml solution for injection
Ephedrine Kabi 10 mg/ml solution for injection
Ephedrine Kabi 30 mg/ml solution for injection

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 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 Kabi is and what it is used for

Ephedrine Kabi contains the active substance ephedrine hydrochloride.
Ephedrine belongs to a group of medicines called sympathomimetics. Sympathomimetic drugs affect the part of your nervous system that works automatically.
Ephedrine Kabi 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 children (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 Kabi

Your doctor will not give you Ephedrine Kabi if:
- you are allergic to ephedrine 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 given Ephedrine Kabi 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 Kabi
Tell your doctor, nurse or pharmacist if you are taking, have recently taken or might take any other medicines.

This is especially important for the following medicines:
- methylphenidate, used to treat "attention deficit hyperactivity disorder (ADHD)";
- other vasoconstrictors such as phenylpropanolamine or pseudoephedrine (medicines used in nasal decongestant), phenylephrine (a medicine used to treat hypotension);
- alpha- and beta-adrenergic blocking agents (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 for treating migraine;
- 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
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
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

Ephedrine Kabi 3 mg/ml Solution for injection contains sodium
This medicine contains 3.21 mg of sodium (main component of cooking/table salt) in each ml. This is equivalent to 0.16% of the recommended maximum daily dietary intake of sodium for an adult.
This medicine contains 32.1 mg of sodium (main component of cooking/table salt) in each 10 ml ampoule. This is equivalent to 1.6% of the recommended maximum daily dietary intake of sodium for an adult.

Ephedrine Kabi 10 mg/ml Solution for contains sodium
This medicine contains 2.36 mg of sodium (main component of cooking/table salt) in ml. This is equivalent to 0.12% of the recommended maximum daily dietary intake of sodium for an adult.
This medicine contains 11.8 mg of sodium (main component of cooking/table salt) in 5 ml ampoule. This is equivalent to 0.59% of the recommended maximum daily dietary intake of sodium for an adult.

Ephedrine Kabi 30 mg/ml Solution for injection
This medicine contains less than 1 mmol sodium (23 mg) per ml, that is to say essentially 'sodium-free'.

3. How you will be given Ephedrine Kabi

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 for 3 mg/ml
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.

Adults and elderly for 10 mg/ml
You will be given a slow injection of 5 mg (maximum 10 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.

Adults and elderly for 30 mg/ml
You will be given a slow 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.

The 10mg/ml and 30 mg/ml strengths should be diluted before use.

Use in children and adolescents
• Children under 12 years
Ephedrine Kabi 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 (feeling the heart beat), 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 affects you can help provide more information on the safety of this medicine.

5. How to store Ephedrine Kabi

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 after "EXP". The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

After opening the ampoule the product must be used immediately, however the non-diluted solution can be stored in a syringe for 72 hours at 25 °C and for 72 hours at 2 to 8 °C.
The diluted product is stable for 72 hours at 25 °C and for 72 hours at 2 to 8 °C.

Do not use this medicine if you notice particles in the solution.

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 Kabi contains

The active substance is ephedrine hydrochloride.

One ml of solution for injection contains 3 mg ephedrine hydrochloride.
Each 10 ml glass ampoule contains 30 mg ephedrine hydrochloride.
- The other ingredients are sodium chloride, sodium citrate dihydrate, citric acid monohydrate, Sodium Hydroxide (for pH adjustment), Hydrochloric Acid (for pH adjustment) and water for injections

One ml of solution for injection contains 10 mg ephedrine hydrochloride.
Each 5 ml glass ampoule contains 50 mg ephedrine hydrochloride.
- The other ingredients are sodium chloride, Sodium Hydroxide (for pH adjustment), Hydrochloric Acid (for pH adjustment) and water for injections

One ml of solution for injection contains 30 mg ephedrine hydrochloride.
Each 1 ml glass ampoule contains 30 mg ephedrine hydrochloride.

- The other ingredients are Sodium Hydroxide (for pH adjustment), Hydrochloric Acid (for pH adjustment) and water for injections

What Ephedrine Kabi looks like and contents of the pack
Ephedrine Kabi is a clear, colourless to pale yellow solution for injection.

Ephedrine Kabi 3 mg/ml Solution for injection is available in 10 ml glass ampoules.
Pack sizes of 5 and 10 ampoules

Ephedrine Kabi 10 mg/ml Solution for injection is available in 5 ml glass ampoules
Pack sizes of 5 and 10 ampoules

Ephedrine Kabi 30 mg/ml Solution for injection is available in 1 ml glass ampoules
Pack sizes of 5, 10 and 50 ampoules

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Fresenius Kabi Deutschland GmbH
Else-Kröner-Strasse 1,
61352 Bad Homburg v.d.Höhe
Germany

Manufacturer

Labesfal – Laboratórios Almiro
S.A. Zona Industrial do Lagedo
Santiago de Besteiros, 3465-157
Portugal

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The following information is intended for healthcare professionals only:

Therapeutic indications
Treatment of hypotension from spinal, epidural and general anaesthesia.

Posology and method of administration
<u>Posology 3 mg/ml</u>
<u>Adults</u>
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 total dose administered over 24 hours must not exceed 150 mg.

<u>Posology 10 mg/ml</u>
<u>Adults</u>

Slow intravenous injection of 5 mg (maximum 10 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 total dose administered over 24 hours must not exceed 150 mg.

Posology 30 mg/ml
Adults
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 total dose administered over 24 hours must not exceed 150 mg.

Paediatric population
Ephedrine 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.

Elderly
As for adults.

Method of Administration
Ephedrine injection must be used solely by or under the supervision of the anaesthetist as an injection via intravenous route.
The medicinal product should be diluted before use as applicable (see Preparation).
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/L.

Management
The management of ephedrine overdose with this product may require intensive supportive treatment. Slow intravenous injection of labetalol 50-200mg may be given with electrocardiograph monitoring for the treatment of supraventricular tachycardia. Marked hypokalaemia (<2.8mmol/L) due to compartmental shift of potassium predisposes to cardiac arrhythmias 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.

Preparation

For single use only.
Dilution instructions 10mg/ml:
Dilute the solution for injection to final concentration of 5 mg/ml as appropriate as described in Posology and method of administration.

Dilution instructions 30 mg/ml:
Dilute the solution for injection to final concentration of 3mg/ml or 5 mg/ml as appropriate as described in Posology and method of administration.

Ephedrine is compatible with:

- sodium chloride 9 mg/ml (0.9% w/v)
- glucose 50 mg/ml (5% w/v) infusion
- Ringer Lactate infusion

Shelf life

Unopened: 3 years.

Shelf life after opening the ampoule:
The product must be used immediately

Shelf-life for non-diluted solution when stored in syringe:
Chemical and physical in-use stability has been demonstrated for 72 hours at 25 °C and for 72 hours at 2 to 8 °C.

Shelf life after dilution:
Chemical and physical in-use stability has been demonstrated for 72 hours at 25 °C and for 72 hours at 2 to 8 °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.