Ephedrine Hydrochloride 30mg per 1ml Solution for Injection

Ephedrine Hydrochloride (referred to as "Ephedrine Injection" in this leaflet)

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, please ask your doctor, pharmacist or nurse. This includes any possible side effects mentioned in the 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
4. Possible side effects
5. How to store Ephedrine Injection
6. Contents of the pack and other information

What is Ephedrine Injection and what is it used for?
Ephedrine belongs to a group of medicines called sympathomimetics. Sympathomimetics 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 for temporarily reducing the blood supply to small blood vessels.

Ephedrine Injection may be used in conditions including:
• Indications:
  - In combination with other indirect sympathomimetic agents such as phenylpropanolamine, phenylephrine, pseudoephedrine (pseudoephedrine is also an allergic reaction to pseudoephedrine). (measures used to treat "attention deficit hyperactivity disorder" (ADHD)).
  - To treat low blood pressure.
  - You are told to take in the last 14 days - a non-selective monoamine oxidase inhibitor (MAOls) (inhibits sympathomimetic agents used to treat depression).
  - High blood pressure.
  - You have an overactive thyroid gland (hyperthyroidism);
  - You have diabetes;
  - You suffer from heart disease or any other heart conditions , including angina;
  - You suffer from diabetes;
  - You have had a heart attack or have had other heart conditions, including angina;
  - You have a history of heart disease;
  - You have a narrowing and/or blockage of blood vessels;
  - You have had a heart attack;
  - You have 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;

Ephedrine Injection should be used with caution in patients who may be unsuitable for sympathomimetic agents, particularly those with hypertensive. Ephedrine may be used with caution in patients: with cardiac disease such as ischaemic heart disease, arrhythmia or tachycardia, occlusive vascular disease including arteriosclerosis, hypertension, or anaemia. Apnoea may be precipitated in patients under anaesthesia.

Caution is also required when Ephedrine is given to patients with diabetes mellitus, closed angle glaucoma or prostatic hypertrophy.

Ephedrine Injection should be avoided or used with caution in patients undergoing anaesthesia with propofol or halothane, or other halogenated anaesthetics, as such may induce positive results in anti-doping controls.

Laboratory Testing
If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

Continued overleaf

Use in children:
The paediatric dose will be given as a slow injection into the vein of either 0.5-0.75mg per kg of body weight or 17.5mg per square metre of body surface area.

Parents with kidney or liver diseases:
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.

Continued overleaf

Use in pregnancy and breastfeeding:
If you are pregnant or breast feeding, think you may be pregnant or planning to have a baby, ask your doctor, pharmacist or nurse for advice before being given this medicine.

Labelling and marketing information is included for healthcare professionals only

Ephedrine Hydrochloride 30mg per 1ml Solution for Injection

Ephedrine Hydrochloride

Indications:
Therapy for hypertension from spinal or epidural anaesthesia.

Dose
Adults and the elderly
Up to 20 mg in increments of 5-7.5 mg.

By slow intravenous administration, after development of hypotension.

Children
Up to 0.5mg per kg body weight or 17.25mg per square metre of body surface area. By slow intravenous administration, after development of hypotension.

Contra-indications:
The following conditions must be noted in cases of hypotension to epinephrine:

- In combination with other indirect sympathomimetic agents such as phenylpropanolamine, phenylephrine, pseudoephedrine.

- In combination with alpha sympathomimetic agents.

- In combination with non-selective MAO inhibitors or within 14 days of their withdrawal.

If you are currently taking or have taken within the last 14 days any monoamine oxidase inhibitor medicine used to treat depression, or if you suffer from diabetes;

- You suffer from heart disease or any other heart conditions, including angina;

- You suffer from diabetes;

- You have a history of heart disease;

- You have a narrowing and/or blockage of blood vessels;

- You have had a heart attack;

- You have 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 have an overactive thyroid gland (hyperthyroidism);

- You have diabetes;

- You suffer from heart disease or any other heart conditions, including angina;

- You suffer from diabetes;

- You have a history of heart disease;

- You have a narrowing and/or blockage of blood vessels;

- You have had a heart attack;

- You have 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 suffer from heart disease or any other heart conditions, including angina;

- You suffer from diabetes;

- You have a history of heart disease;

- You have a narrowing and/or blockage of blood vessels;

- You have had a heart attack;

- You have 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;

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- You suffer from diabetes;

- You have a history of heart disease;

- You have a narrowing and/or blockage of blood vessels;

- You have had a heart attack;

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- You have had a heart attack;

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- You are about to have an operation which requires that you are given an anaesthetic;
4. POSSIBLE SIDE EFFECTS

Like all medicines Ephedrine injection can cause side effects, although not everybody gets them.

Possible side effects include:
- palpitations, hypertension, tachycardia
- increased heart rhythm
- palpitations, high blood pressure, fast heartbeat, or
- pain over the heart, slow heartbeat, low blood pressure;
- heart failure (cardiac arrest);
- breathing in the brain;
- build-up of a fluid in 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 relaxed, depression;
- weakness, dizziness, sleepiness, sweating;
- loss of appetite, bloating;
- abdominal pain, nausea, vomiting
- diarrhoea;
- rash, itching; skin problems;
- urinating too much or too little;
- feeling cold

Not Known: Frequency cannot be estimated from the available data
- effects on blood clotting;
- allergy (hypersensitivity);
- changes in your personality or the way you feel/think; fear;
- increased saliva production;
- reduced appetite;
- a decrease in blood potassium levels; changes in blood sugar levels

5. How to Store Ephedrine injection

Store in a cool dry place. Do not store above 25°C. Keep the outer carton in order to protect from light. Do not store above 2°C. Keep in the outer carton in order to protect from light. This medicine will only be used for your treatment. Your doctor will dispose of any left over medicine.

6. Contents of the pack and other information

What Ephedrine injection contains

The active ingredient is Ephedrine hydrochloride (3%w/v), equivalent to 35mg ephedrine hydrochloride in 1ml solution.

The other ingredient is water for injection.

What Ephedrine injection looks like and contents of the pack

Ephedrine Injection is a clear, colourless solution for injection supplied to your doctor or pharmacist in a pack of 10 clear glass ampoules, each containing 1ml of medicine.

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: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5.1 Side effects

5.1.1 Common side effects

Common: palpitations, hypertension, tachycardia

Cardiac disorders:
- Not known: episodes of angle-closure glaucoma

Eye disorders:
- Not known: tremor, hypersalivation

Common: confusion, anxiety, depression

Not known: hypersensitivity

Immune system disorders:
- Blood and lymphatic system disorders:
- Therefore, ephedrine should be avoided or used with caution, and only if necessary, during pregnancy.

Side effects

Blood and hematological system disorders:
- Not known: primary haematological manifestations
- Immune system disorders
- Neurological disorders

Psychiatric disorders
- Not known: anxiety, depression
- Not known: psychotic state, fear

Respiratory system disorders
- Not known: wheezing

Digestive system disorders
- Not known: diarrhoea
- Hypertension
- Not known: hyperglycaemia

Renal and urinary disorders
- Not known: acute urinary retention

Gastrointestinal disorders:
- Not known: pulmonary oedema
- Hypertensive disorders
- Renal and urinary disorders
- Not known: renal failure
- Not known: reduced appetite

Hypertensive disorders
- Not known: hypokalaemia

Investigations:
- Not known: changes in blood glucose levels

Overdose:
- Symptoms

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 60mg/kg body weight.

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The treatment of ephedrine overdose with this product may require intensive support treatment.

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As with any sympathomimetic agent, ephedrine stimulates the alpha and beta receptors and indirectly by increasing the cardiac output and peripheral resistance, the heart rate is increased.

ATC Code: C01CA26

Adrenergic and Dopaminergic Agent

Pharmacotherapeutic group:

Ephedrine is an adrenergic and dopaminergic agent acting directly on the alpha and beta receptors and indirectly by increasing the cardiac output and peripheral resistance.

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Pharmacodynamics:

Ephedrine is a sympathomimetic amine acting directly on the alpha and beta receptors and indirectly by increasing the cardiac output and peripheral resistance.

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This refers to the last day of that month. Your doctor or nurse will inform you of the expiry date on the ampoule label and carton after EXP.

The choice of antihypertensive drug is dependent on availability, concomitant conditions and the clinical status of the patient.

Pharmacokinetics:

Ephedrine is a sympathomimetic amine acting directly on the alpha and beta receptors and indirectly by increasing the cardiac output and peripheral resistance.

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