Ephedrine Hydrochloride 30mg per 1ml 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 it again.
- If you have any further questions, please 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.

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

Ephedrine Injection belongs to a group of medicines called sympathomimetics. Sympathomimetic 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 by increasing the heart rate and the amount of blood pumped with each beat.

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

- You should not be given Ephedrine Injection if:
  - you suffer from heart disease or any other heart conditions, including angina.
  - you suffer from weakness in a blood vessel wall (leading to a blood developing (unrelated).
  - you have a heart condition.
  - you have a history of heart attack or stroke.
  - you have a heart murmur or blockage of blood vessels.
  - you have chronic bronchitis.
  - you have an overactive thyroid gland (hyperthyroidism).
  - you have or suspect that you suffer from glaucoma increased pressure in your eye (glaucoma).
  - you are about to have an operation which requires that you are given an anaesthetic.

- You should not be given Ephedrine Injection if you:
  - are allergic to ephedrine hydrochloride or to any of the other ingredients in this medicine, listed in section 6.
  - are taking another indirect sympathomimetic agent such as phenylephrine, pseudoephedrine or phenylpropanolamine (medicine used to treat congestion in the sinuses due to cold or allergy). Ephedrine Injection is usually given by slow intravenous administration, after development of hypotension.

- Do not give Ephedrine Injection to:
  - infants.
  - children.
  - unless your doctor or nurse tells you to.

- You should not be given Ephedrine Injection if you:
  - are taking or have taken in the last 14 days any of the following medicines:
    - linezolid, used to treat infections.
    - selective MAO-A inhibitors (administered concomitantly or more than 14 days).
    - direct stimulators of alpha receptors of the sympathetic nervous system.
    - any other medicines which may interact with Ephedrine Injection.
    - medicines used to treat hypertension.
    - any other medicines which may interact with Ephedrine Injection.
    - medicines used to treat depression.
  - you are taking or have taken in the last 14 days a non-selective monoamine oxidase inhibitor (MAO) (medicine used to treat depression).
  - you are receiving cardiac glycosides, other halogenated anaesthetics, as they may induce ventricular fibres.
  - you are receiving corticosteroids, a type of medicine used to relieve swelling in a number of different conditions.
  - you are being treated with sympathomimetic agents.

3. How Ephedrine Injection is given

This medicine is injected into a vein. Your dose may be repeated until the maximum amount of medicine (30mg) is given.

4. Possible 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. See section 4.

5. Contents of the pack and other information

The usual starting dose is 1-3.5mg given slowly into a vein. Your dose may be repeated until the maximum amount of medicine (30mg) is given.

6. Contents of the pack and other information

- The carton contains:
  - 10 vials of Ephedrine Injection 30mg per 1ml Solution for Injection.
  - 100mm Measurement Verification Bar.

- If you think you have been given too much Ephedrine Injection:
  - Call your doctor, pharmacist or nurse immediately.

- 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 giving this medicine.

- Laboratory Testing

Some of these medicines contain an active ingredient that can cause drug levels to be falsely high in anti-dopamine tests.

- Pregnancy, breast-feeding and fertility

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 giving this medicine.

- Medicines containing sympathomimetics

Many sympathomimetics interact with monoamine oxidase inhibitors, and should not be given to patients receiving such treatment or within 14 days of its termination. It is advisable to avoid sympathomimetics when taking monoamine oxidase inhibitors.

- Contraindications

Ephedrine injection is contraindicated with high doses of lithium agents may result in increased susceptibility to digitalis-induced arrhythmias. Hypokalaemia may be enhanced by concurrent administration of amiloride or other thiazide-like diuretics, or by diuretic therapy.

- Warnings

Ephedrine should be used with caution in patients who may be particularly susceptible to side effects of sympathomimetics, particularly those with hypertension or hypertensive crises. Ephedrine is not indicated in patients with a history of cardiac disease or hypertension.

- Adverse reactions

Many sympathomimetics interact with monoamine oxidase inhibitors, and should not be given to patients receiving such treatment or within 14 days of its termination. It is advisable to avoid sympathomimetics when taking monoamine oxidase inhibitors.

- For parents or carers of children

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- Other medicines which may interact with Ephedrine Injection:
Possible side effects include:
- Not known: psychotic states, fear
- Common: confusion, anxiety, depression
- Not known: hypersensitivity

Blood and lymphatic system disorders:
- Side effects:
  - the benefit of therapy for the woman.
  - taking into account the benefit of breastfeeding for the child and
  - be made on whether to avoid ephedrine therapy or lactation
  - There is evidence that ephedrine is eliminated within 21 to 42
  - Ephedrine is excreted in breast milk. Irritability and disturbed
  - Breast-feeding:
  - and only if necessary, during pregnancy.
  - Increased foetal heart rate and beat-to-beat variability.
  - Isolated cases of maternal hypertension have been described
  - respect to malformation.
  - women appear to indicate no particular effects of ephedrine with
  - Studies in animals have shown a teratogenic effect.
  - Vasopressor action of ephedrine.
  - Hypotensive agents: reserpine and methyldopa may reduce the
  - 4. Possible side effects

Possible side effects that you may experience while taking this

This active ingredient is Ephedrine Hydrochloride 3%/v,

This other ingredient is water for injections.

What Ephedrine Injection looks like and contents of the pack

Ephedrine Injection is a clear, colourless solution for injection

ampoule.

is Ephedrine Hydrochloride 3%/v,

In the absence of compatibility studies, this medicinal product

Incompatibilities:

alkaline at pH = 6.3, the half-life is approximately 6 hours.

The half-life depends on urine pH. When the urine is acidified

Excretion depends on urine pH from 73 to 99% (mean: 88%) in acidic urine,

From 73 to 99% (mean: 88%) in acidic urine,

At pH = 5, the half-life is 3 hours; when the urine is rendered alkaline at pH ≥ 7.3, the half-life is approximately 6 hours.

Incompatible:

This product is for single use only. If only part of the solution is

Do not administer if there are visible signs of deterioration.

Shelf Life:

Ephedrine Hydrochloride 3%/v,

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United Kingdom.

Manufacturer:
McCartan Laboratories Ltd trading as Martindale Pharma,
Bromley Road,
Bromley,
RM3 8UG
United Kingdom.

Product Licence No. PL: 01883/6131

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100mm Measurement Verification Bar

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