

Package Leaflet: Information for the user

Ephedrine Hydrochloride 30mg in 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.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or nurse.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or nurse.

In this leaflet:

1. What Ephedrine Injection is and what it is used for
2. Before Ephedrine Injection is given
3. How Ephedrine Injection is given
4. Possible side effects
5. How to store Ephedrine Injection
6. Further information

This leaflet contains a summary of the information available for this medicine. You should ask your doctor or pharmacist if you are unsure about any aspect of this medicine.

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

Ephedrine 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 anaesthesia. It raises blood pressure by temporarily reducing the blood supply to small blood vessels.

2. Before you are given Ephedrine Injection

You should not be given Ephedrine Injection if:

- you are allergic (hypersensitive) to ephedrine or to any of the other ingredients in this medicine, listed in section 6 of this leaflet
- you suffer from an overactive thyroid gland which can cause increased appetite, weight loss or sweating
- you suffer from prostate gland enlargement
- you suffer from any heart disease
- you suffer from increased pressure in the eye (glaucoma)
- you suffer from diabetes
- you suffer from blood clots
- you suffer from high blood pressure
- you are taking monoamine oxidase inhibitors (MAOIs) (see Taking other medicines).

If any of the above applies to you, please tell your doctor.

Take special care with Ephedrine Injection

Tell your doctor before being given Ephedrine Injection if you have a history of heart disease, irregular heart rhythm or angina.

Taking other medicines

Please tell your doctor or nurse if you are taking, or have recently taken, any other medicine including medicines obtained without prescription.

Other medicines which may interact with Ephedrine Injection are:

- a type of anti-depressant known as monoamine oxidase inhibitors (MAOIs). Tell your doctor or nurse even if you have stopped taking them in the past 2 weeks.

Pregnancy and breast-feeding

Tell your doctor if you are pregnant, trying to become pregnant or breast-feeding before you are given this medicine.

Driving and using machines

Ephedrine Injection is not thought to have any affect on driving or using machines however if you feel at all unwell you should consult your doctor before you begin driving or using machines again.

3. How Ephedrine Injection is given

This medicine is an injection and will be given to you by your doctor. Your doctor will determine the dose you require.

Adults and the elderly:

The usual starting dose is 3-7.5mg given slowly into a vein.

Your dose may be repeated until the maximum amount of medicine (30mg) is given.

Children:

Your child will be given a slow injection into the vein of either 0.5-0.75mg per kg of body weight or 17 25mg per square metre of body surface.

If you think you have been given too much Ephedrine Injection

This medicine is given to you by your doctor so it is unlikely you will receive too much. Your doctor has information on how to recognise and treat an overdose. If you are concerned about your treatment, please talk to your doctor.

If you have any further questions on the use of this product, ask your doctor or nurse.

4. Possible side effects

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

Possible side effects include:

- a light headed or dizzy feeling (giddiness)
- headache
- feeling worried
- restlessness
- problems sleeping
- feeling sick or being sick
- thirst
- sweating
- muscular weakness or shaking
- fast or irregular heartbeat
- heightened sense of your heart beating (palpitations)
- pain over the heart
- difficulty in passing urine.

If you are given too much of this medicine you may:

- see or hear things that aren't there (hallucinations)
- believe in things that aren't true (delusions)
- notice changes in your personality or the way you feel/think.

Although it is not known exactly how often this happens, some people may occasionally experience chest pain (due to heart problems such as angina). Tell your doctor, nurse or midwife if you develop these symptoms whilst receiving treatment with Ephedrine Injection, but do not stop using this medicine unless told to do so.

If any of these side effects get serious, or you notice any other side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to Store Ephedrine Injection

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and ampoule label after EXP. The expiry date refers to the last day of that month. Your doctor or nurse will check this.

Do not store above 25°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. Further information

What Ephedrine Injection contains

The active ingredient is Ephedrine Hydrochloride 3% w/v. Each 1ml ampoule contains 30mg ephedrine hydrochloride.

The other ingredient is water for injections.

What Ephedrine Injection looks like and contents of the pack

This medicine 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.

Marketing Authorisation Holder:

Ethypharm
194, Bureaux de la Colline, Bâtiment D 92213,
Saint-Cloud Cedex, France

Manufacturer:

Macarthy's Laboratories Ltd trading as Martindale
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Fannin Limited
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Marketing Authorisation No.: PA 0549/027/001

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Technical Prescribing Information

Ephedrine Hydrochloride 30mg in 1ml Solution for Injection
Ephedrine Hydrochloride

Indications:

To reduce hypotension during spinal anaesthesia

Dose**Adults and the elderly**

Up to 30 mg in increments of 3 - 7.5 mg.
By slow intravenous administration, after development of hypotension.

Children

0.5 - 0.75 mg / kg body weight or 17 - 25 mg / M² body surface.
By slow intravenous administration, after development of hypotension.

Contra-indications:

Patients receiving treatment with monoamine oxidase inhibitors (or within 2 weeks of their withdrawal).
Coronary thrombosis, diabetes mellitus, ischaemic heart disease, hypertension, thyrotoxicosis, closed angle glaucoma or, in the case of elderly patients prostatic hypertrophy.

Warnings:

Cardiovascular effects may be seen with sympathomimetic drugs including Ephedrine Hydrochloride 30 mg in 1 ml Solution for Injection. There is some evidence from postmarketing data and published literature of rare occurrences of myocardial ischaemia associated with beta agonists. Patients with underlying severe heart disease (e.g. ischaemic heart disease, arrhythmia or severe heart failure) who are receiving Ephedrine Hydrochloride 30 mg in 1 ml Solution for Injection should be warned to seek medical advice if they experience chest pain or other symptoms of worsening heart disease. Attention should be paid to assessment of symptoms such as dyspnoea and chest pain, as they may be of either respiratory or cardiac origin.

Interactions:

Patients receiving treatment with monoamine oxidase inhibitors (or within 2 weeks of their withdrawal).

Pregnancy:

There is no, or inadequate evidence of safety of the drug in human pregnancy, but it has been in use for many years without apparent ill consequence. If drug therapy during pregnancy is needed the use of this drug is acceptable.

Side effects:

Giddiness, headache, nausea, vomiting, sweating, thirst, arrhythmias, tachycardia, precordial pain, palpitations, difficulty in micturition, muscular weakness, tremors, anxiety, restlessness and insomnia. In the case of patients with prostatic hypertrophy the retention of urine may become acute. Myocardial ischaemia has been reported spontaneously in post-marketing data, therefore the frequency is regarded as unknown.

Overdose:**Symptoms**

Giddiness, headache, nausea, vomiting, sweating, thirst, arrhythmias, tachycardia, precordial pain, palpitations, difficulty in micturition, muscular weakness, tremors, anxiety, restlessness and insomnia, paranoid psychosis, delusions and hallucinations may occur.

Treatment

In severe overdosage Diazepam may be required to control CNS stimulation and severe hypertension will require specific therapy.

Pharmaco-dynamics:

Ephedrine is a sympathomimetic agent with direct and indirect effects on adrenergic receptors. It has alpha and betaadrenergic activity and has pronounced stimulating effects on the central nervous system. It causes bronchodilation, relaxes the bladder wall, contracts the sphincter muscles, but relaxes the detrusor muscles.

It has stimulant action on the respiratory centre.

Pharmaco-kinetics:

Ephedrine accumulates in the liver, lungs, kidneys, spleen and brain. It is largely excreted unchanged in the urine together with small amounts of metabolites.

It has a plasma half-life reportedly between 3 and 6 hours depending on the urinary pH; elimination is enhanced and half-life accordingly shorter in acid urine.

Incompatibilities:

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

Shelf life:

36 months unopened. Do not store above 25°C. Keep in outer carton. This is a potent drug, which should be stored carefully. Do not administer if there are visible signs of deterioration.

This product is for single use only. If only part of the solution is used the remainder should be discarded.

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