

**1.4.3. PATIENT INFORMATION LEAFLET (PIL)**

**EPHEVER**

**Ephedrine Hydrochloride Injection BP 50mg,ml-1ml**

**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 of the 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
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

**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 or epidural anaesthesia. It raises blood pressure by temporarily reducing the blood supply to small blood vessels.

**2. WHAT YOU NEED TO KNOW BEFORE YOU USE EPHEDRINE INJECTION** You should not be given Ephedrine Injection if:

- You are allergic to ephedrine hydrochloride or any of the other ingredients of this medicine, (listed in section 6);

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- 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 suffer from diabetes;
- You suffer from heart disease or any other heart conditions, including angina;
- You suffer from weakness in a blood vessel wall leading to a bulge developing (aneurysm);
- You have 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, pharmacist or nurse if you are taking, have recently taken, or might take any other medicines. Ephedrine Injection must not be used with drugs used to treat severe depression, such as phenelzine or moclobemide, or if you are within 2 weeks of discontinuing them. These drugs are known as monoamine oxidase inhibitors (MAOIs). Other medicines which may interact with Ephedrine Injection are:

- 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;

- Anaesthetics that are inhaled, such as halothane;
- Medicines used to treat depression;
- Sibutramine, a medicine used as an appetite suppressant;
- Linezolid, used to treat infections;
- Medicines used to treat asthma such as theophylline;
- Corticosteroids, a type of medicine used to relieve swelling in a variety of different conditions;
- Medicines for epilepsy;
- Doxapram, medicines used to treat breathing problems;
- Oxytocin, a medicine used during labour;
- Reserpine and methyldopa and related medicines, used to treat high blood pressure;
- Guanethidine and related medicines, used to treat high blood pressure;
- 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)

**Therapeutic indications** Reversal of hypotension from spinal or epidural anaesthesia.

**Administration** Intravenous or intra muscular use.

**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 being given this medicine.

### 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 and how and when the injection will be given. Patients with kidney or liver disease 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.

**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, this medicine can cause side effects, although not everybody gets them. Possible side effects include: If you get any of the following side effects, stop taking this medicine and seek urgent medical advice straight away:

- Difficulty in breathing;
- 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:**

**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 (hypersensitivity);
- Changes in your personality or the way you feel/think, fear;
- Tremor, excessive saliva production;
- reduced appetite;
- A decrease in blood potassium levels; changes in blood sugar levels.

#### **5. HOW TO STORE EPHEDRINE INJECTION**

Store at a temperature not exceeding 30°C. Protect from light.

#### **6. CONTENTS OF THE PACK AND OTHER INFORMATION**

##### **What Ephedrine Injection contains –**

The active substance is ephedrine hydrochloride. Each 1 ml of solution for injection contains 30 mg ephedrine hydrochloride. - The other ingredients are :-

Sodium Metabisulphite

Di sodium E.D.T.A

Sodium Chloride

Tri sodium Citrate Dihydrate

Citric Acid (Anhydrous)

water for injections.

**What Ephedrine Injection looks like and contents of the pack**

A clear, colourless solution filled in 1.0 ml amber glass ampoules.

**Carton packs containing:** 10 Amber glass vials of 2ml.

**Administration:** For intravenous infusion, intravenous injection or intramuscular injection.

**Shelf life:** 24 months.

For single use only. Discard any unused product.

**MARKETING AUTHORISATION HOLDER AND MANUFACTURING SITE  
ADDRESSES**

**Marketing Authorisation Holder**

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