Efedrin Stragen 3mg/ml, solution for injection
Ephedrine hydrochloride

Read all of this leaflet carefully before you start using 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 or pharmacist.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:
1. What Efedrin Stragen is and what it is used for
2. What you need to know before you are given Efedrin Stragen
3. How Efedrin Stragen is given
4. Possible side effects
5. How to store Efedrin Stragen
6. Contents of the pack and other information

1. What Efedrin Stragen is and what it is used for

Efedrin Stragen is used to treat low blood pressure that can occur during different types of anaesthesia. This product must be used solely by or under the supervision of the anaesthetist.

2. What you need to know before you use Efedrin Stragen

You can not be given Efedrin Stragen:
- if you are allergic to ephedrine or to any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

You should inform your doctor if:
- you have high blood pressure;
- you suffer from heart disease or any other heart conditions;
- you have diabetes;
- you have an overactive thyroid gland
- you have an enlarged prostate;
- you know or suspect that you suffer from glaucoma (increased pressure inside the eye);
- you are currently taking or have taken, within the last 14 days, any monoamine oxidase inhibitors medicine (MAOIs) used to treat depression.

Other medicines and Efedrin Stragen

Tell your doctor if you are taking or have recently taken or might use any other medicines.

It is especially important to tell your doctor if you are taking the following medicines:
- Antidepressant medicines, such as tricyclic antidepressant (e.g. imipramine) or serotoninergergic-noradrenergic medicines (e.g. minalcipran, venlafaxine) or any monoamine oxidase inhibitors (e.g. moclobemide, toloxatone);
- Medicines used to lower the blood pressure (e.g. guanethidine, clonidine);
- Theophylline, a medicine used for respiratory diseases such as asthma;
- Corticosteroids, which are medicines that reduce the inflammation and the consequences of allergic reactions;
- Sibutramine, an appetite suppressant that is administered orally for the treatment of obesity;
- Linezolide, an antibiotic used for the treatment of serious infections;
- Oxytocin, a medicine used during labour.
- Some other anaesthetics and especially cyclopropane and halothane;
- Some cough and cold medication that can elevate the blood pressure (phenylpropanolamine, pseudoephedrine, phenylephrine);
- Methylphenidate, a medicine used for the treatment of attention deficit-hyperactivity disorder;
- Some medicines used for the treatment of heart failure and/or irregular heartbeat (Cardiac glycosides, Quinidin)

**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. Efedrin Stragen may be used under caesarean section.
You should suspend breast feeding for a few days after receiving this medicine.

**Efedrin Stragen contains sodium**
This medicine contains 3.32 mg (0.144 mmol) of sodium per ml of injection (a total of 33.2 mg or 1.44 mmol sodium in 10 ml syringe). This amount must be taken into consideration by patients on a salt-restricted diet.

3. **How to use Efedrin Stragen**
Your doctor or nurse will give Efedrin Stragen to you into a vein (intravenous route). Your doctor will decide the correct dosage for you and when and how the injection should be administered.

**If you are given more Efedrin Stragen than you should**
having too much of Efedrin Stragen may lead to symptoms such as feeling sick (nausea), vomiting, fever, paranoid psychosis, irregular heart beat, high blood pressure, decreased rate of breathing, fits and coma. If these symptoms occur, you may require intensive supportive treatment.

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

*For practical information on handling or administration of the medicinal product, please refer to the section for medical or healthcare professionals at the end of the leaflet.*

4. **Possible side effects**
Like all medicines, Efedrin Stragen can cause side effects, although not everybody gets them.

**Common** (may affect up to 1 in 10 people):
- confusion, anxiety, depression;
- nervousness, irritability, restlessness, weakness, difficulty in sleeping (insomnia), headache, sweating;
- feeling your heartbeat (palpitations), high blood pressure (hypertension), increased heart beat (tachycardia);
- laboured breathing (dyspnoea);
- feeling sick (nausea), vomiting.

**Rare** (may affect up to 1 in 1,000 people):
- irregular heart beat (cardiac arrhythmias);
- lack of ability to urinate (acute urinary retention).
Not known (frequency cannot be estimated from the available data):
- allergic reactions (hypersensitivity);
- psychotic states, fear;
- shaking (tremor), elevated production of saliva (hypersalivation);
- episodes of angle-closure glaucoma (a disease in which the optic nerve is damaged);
- chest pain, slower heart beat (reflex bradycardia), cardiac arrest, lower blood pressure (hypotension);
- bleeding, within the skull (cerebral haemorrhage);
- fluid accumulation in the lungs (pulmonary oedema);
- reduced appetite;
- low blood levels of potassium (hypokalaemia), which can cause muscle weakness, twitching or abnormal heart rhythm changes in blood glucose levels.

Reporting of side effects
If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Efedrin Stragen

Keep out of the sight and reach of children.

Do not use Efedrin Stragen after the expiry date which is stated on the carton and syringe label, after “EXP”. Your doctor or nurse will check this.

Store the blister in the outer carton in order to protect from light.

The pre-filled syringe is for single use only.

After opening the product must be used immediately.

Any unused product or waste material should be disposed of in accordance with local requirements.

6. Contents of the pack and other information

What Efedrin Stragen contains
- The active ingredient is ephedrine hydrochloride. Each ml of solution for injection contains 3 mg ephedrine hydrochloride. Each 10 ml prefilled syringe contains 30 mg ephedrine hydrochloride.
- The other ingredients are sodium chloride, citric acid monohydrate, sodium citrate, water for injection, hydrochloric acid or sodium hydroxide (for pH adjustments).

Each ml of solution for injection contains 3.32 mg sodium equivalent to 0.144 mmol.

What Efedrin Stragen looks like and contents of the pack
Efedrin Stragen is a clear and colourless solution. It is supplied in a 10 ml polypropylene prefilled syringe with a polypropylene tip cap and tamper proof seal, and is individually packaged in a transparent blister pack.
The prefilled syringes are available in boxes of 10 or 12 syringes.
Not all pack sizes may be marketed.
The following information is intended for medical or healthcare professionals only:

Instructions for use:

Be careful to strictly respect the protocol for the use of the syringe.

The pre-filled syringe is for single patient only.
Discard syringe after use. DO NOT REUSE.
The content of un-opened and un-damaged blister is sterile, and must not be opened until use.
The product should be inspected visually for particles and discoloration prior to administration. Only clear colourless solution free from particles or precipitates should be used.
Do not use the product if the tamper evident seal on syringe is broken.
Using aseptic technique, Efedrin Stragen can be used on a sterile field.

Withdraw the pre-filled syringe from the sterile blister.

1. Before opening the syringe, push firmly the piston rod in order to break loose the syringe plunger.
2. Twist off the tip cap to break the frangible obturator.

3. Check that the sealing cap has been completely removed.

4. Purge the air of the syringe by pushing the piston slightly.

5. Connect the syringe to the intravenous access. Push the piston carefully to inject the required volume.

Any unused product or waste material should be disposed of in accordance with local requirements.

Storage:
After opening: the product must be used immediately.
Store the blister in the outer carton in order to protect from light.