PACKAGE LEAFLET: INFORMATION FOR THE USER

EPHEDRINE HCl STEROP 10mg/ml
EPHEDRINE HCl STEROP 50mg/ml
Solution for injection

Ephedrine Hydrochloride

Read all of this leaflet carefully before you start using this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:
1. What Ephedrine HCl Sterop is and what it is used for
2. What you need to know before you use Ephedrine HCl Sterop
3. How to use Ephedrine HCl Sterop
4. Possible side effects
5. How to store Ephedrine HCl Sterop
6. Further information

1. WHAT EPHEDRINE HCl STEROP IS AND WHAT IT IS USED FOR

Ephedrine is a sympathicomimetic agent and a cardiac stimulant excluding cardiac glycosides.

EPHEDRINE HCl STEROP is a solution for injection in ampoules used for:
- treatment and prevention of hypotension during general anesthesia and loco-regional anesthesia, accompanied or not by a reduction of the cardiac rhythm, practiced for a surgical or obstetric act considering that anesthesia is rachidian or epidural.
- exceptionally, in the symptomatic treatment of severe acute bronchospasm in bronchial asthma.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE EPHEDRINE HCl STEROP?

Do not use Ephedrine HCl Sterop
- if you are allergic (hypersensitive) to ephedrine.
- if you present hyperexcitability, a tumor secreting hypertensive substances (pheochromocytoma), a hardening and a thickening of the walls of arteries (arteriosclerosis) and an abnormal deformation of arterial walls (aneurysm).
- in association with phenylpropanolamine, phenylephrine, pseudoephedrine, methylphenidate (other indirect sympathicomimetics).

Take special care with Ephedrine HCl Sterop
Caution is recommended in patients presenting:
- diabetes,
• a too high blood pressure (hypertension),
• an enlargement of the prostate (hypertrophy of the prostate),
• an abnormal and uncontrolled increase of the thyroid functioning (uncontrolled hyperthyroidism),
• a coronary insufficiency and chronic cardiac pathologies,
• a narrow-angle glaucoma.

Ephedrine must be used with precaution in patients having cardiac past history.

This drug product is generally inadvisable in case of association with volatile halogenous anesthetics, with imipraminic antidepressants, serotoninergic-noradrenergic antidepressants, guanethidine and related products.

Ephedrine must be avoided or used very carefully in patients treated or having been treated by an monoamine oxidase inhibitor or during the 14 days following the discontinuation of this treatment.

Sportsmen: the sportsmen’s attention will be drawn by the fact that the active substance induces a positive reaction of the tests practiced during anti-doping controls.

If you are already taking other medicines, please also read the section, “Using other medicines.” Please consult your doctor if one of the warnings listed below is applicable to you, or if it has been in the past.

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

It is inadvisable to associate ephedrine with other vasoconstrictors (phenylpropanolamine, pseudoephedrine, phenylephrine, methylphenidate), with α- and β-adrenergic blocking agents, with volatile halogenous anaesthetics, imipraminic antidepressants, serotoninergic-noradrenergic antidepressants, guanethidine and related products. It is recommended to take precautions for patients receiving an association of ephedrine and MAOI, and also with reserpine, methyldopa or theophylline derivates.

Ephedrine HCl Sterop with food and drink
Not relevant.

Pregnancy and breast-feeding
Pregnancy
This drug will be used during pregnancy only if necessary. Ask your doctor or pharmacist for advice before taking any medicine.

Breast-feeding
Although no specific data is available on this subject, it is supposed that ephedrine crosses the placental barrier and passes into the mother's milk. Taking into account the administration methods of this drug product, breast-feeding is possible and is left to the judgement of the doctor. Ask your doctor or pharmacist for advice before taking any medicine.
Driving and using machines
Not relevant.

Important information about some of the ingredients of Ephedrine HCl Sterop
Not relevant.

3. HOW TO USE EPHEDRINE HCl STEROP

Mode of administration:
Subcutaneous, intramuscular or intravenous way of injection.
The way of injection must be individually determined according to the patient’s needs.

Posology:

Adults:
For the treatment of hypotension, as a pressing agent:
Ephedrine must be administered using the weakest effective dose during a period as short as possible.
- by intramuscular or subcutaneous way: 25 to 50mg, to be repeated if necessary with a maximum dose of 150mg per 24h.
- by intravenous way: 10 to 25mg by slow injection to be repeated if necessary after 10 minutes until a maximum amount of 150mg per 24h.

For the treatment of a severe acute bronchospasm:
The smallest effective dose must be administered by intravenous way: 12.5 to 25mg by slow direct injection.

The doses indicated must be administered according to the patient’s answer.

Children:
The dose is 0.2 to 0.3mg/kg by intramuscular or slow intravenous way every 4 to 6 hours.

If you use more Ephedrine HCl Sterop than you should
If you used too much Ephedrine HCl Sterop, immediately contact your doctor, your pharmacist or the Anti-poison Centre (070/245.245).

Headaches, nauseas, vomiting, too high blood pressure (hypertension), cardiac rhythm faster than normal (tachycardia), fever, paranoid psychosis, hallucinations, disorders of the ventricular and supra-ventricular rhythm, respiratory depression, convulsions and coma can be observed following an ephedrine overdose.
The lethal dose in man is about 2g corresponding to blood concentrations of about 3.5 to 20mg/l.

To treat the overdose and to control stimulation of the central nervous system and convulsions, diazepam can be used in doses from 0.1 to 0.2mg/kg per injection. A dose from 10 to 20mg may be administrated by intramuscular or slow intravenous way.
To treat excitation, hallucinations and hypertension, chlorpromazine may be administrated.
To treat severe hypertension, phentolamine or another α-blocking agent of the adrenergic receptors may be administrated.
To treat a hypertension or a serious tachyarrhythmia, a β-blocking agent, like propranolol, can be interesting.

**If you forget to use Ephedrine HCl Sterop**
Do not use a double dose to make up for a forgotten dose.

### 4. POSSIBLE SIDE EFFECTS

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

The frequency of the possible side effects is defined as following:
- **very common:** affects more than one patient out of 10
- **common:** affects 1 to 10 patients out of 100
- **uncommon:** affects 1 to 10 patients out of 1 000
- **rare:** affects 1 to 10 patients out of 10 000
- **very rare:** affects less than 1 patient out of 10 000
- **not known:** the frequency cannot be estimated from the available data.

During the treatment by Ephedrine HCl Sterop, it is possible to observe the following side effects:

**Very common in anatomically predisposed subjects:**
- crisis of narrow-angle glaucoma.

**Common:**
- modifications of the coagulation parameters (primary haemostasis)
- insomnia, nervousness
- allergy (reactions of hypersensitivity)

**Uncommon:**
- tremors, sudation
- tachycardia, palpitations
- nauseas, vomiting
- difficulty to urinate (acute urinary retention)
- headache

**Rare:**
- anxiety
- cardiac arrhythmias, too high blood pressure (hypertension), precordial pain

**Not known:**
- irritability
- confusion, depression
- muscular weakness

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.
5. HOW TO STORE EPHEDRINE HCl STEROP
Keep out of the reach and sight of children.

Expiry date
Do not use Ephedrine HCl Sterop after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Storage conditions
No special storage condition.
This product contains no preservative and must be used immediately after opening.

Do not use the solution if you notice particles or a precipitate in the ampoule.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Ephedrine HCl Sterop contains

The active substance is:
EPHEDRINE HCl STEROP 10mg/ml: Each ml of solution contains 10mg Ephedrine hydrochloride.
EPHEDRINE HCl STEROP 50mg/ml: Each ml of solution contains 50mg Ephedrine hydrochloride.
The other ingredients are sodium chloride (only for Ephedrine HCl Sterop 10mg/ml) and water for injection.

What Ephedrine HCl Sterop looks like and contents of the pack
Ephedrine HCl Sterop is a solution for injection.
Glass 1ml-ampoules containing 1ml solution. Boxes of 5, 10 ampoules (public) or 100 ampoules (hospital use).

Marketing Authorisation Holder and Manufacturer
Laboratoires STEROP - Avenue de Scheut 46-50 - B-1070 Brussels - BELGIUM.

Medicine under medical prescription.

Registration numbers:
EPHEDRINE HCl STEROP 10mg/ml: BE369564
EPHEDRINE HCl STEROP 50mg/ml: BE369573

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