

PACKAGE LEAFLET: INFORMATION FOR THE USER

Name of the medicinal product

EPHEDRINE AGUETTANT 3 mg/ ml, solution for injection in pre-filled syringe

Ephedrine hydrochloride

Box

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, pharmacist or nurse.

This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.

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.

What is in this leaflet

1. What EPHEDRINE AGUETTANT 3 mg/ml solution for injection in pre-filled syringe is and what it is used for
2. What you need to know before you take EPHEDRINE AGUETTANT 3 mg/ml solution for injection in pre-filled syringe
3. How to use EPHEDRINE AGUETTANT 3 mg/ml solution for injection in pre-filled syringe
4. Possible side effects
5. How to store EPHEDRINE AGUETTANT 3 mg/ml solution for injection in pre-filled syringe
6. Contents of the pack and other information.

1. WHAT EPHEDRINE AGUETTANT 3 mg/ml solution for injection in pre-filled syringe is AND WHAT IT IS USED FOR

Pharmacotherapeutic group: Cardiac stimulants, cardiac glycosides excluded, ATC code: C01CA26.

EPHEDRINE AGUETTANT 3 mg/ml solution for injection in pre-filled syringe is indicated in the following cases:

- Treatment of hypotension during general anaesthesia and loco-regional anaesthesia, whether spinal or epidural and whether for surgical or obstetric procedures,
- Preventative treatment of hypotension during spinal anaesthesia for surgical or obstetric procedures

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE EPHEDRINE AGUETTANT 3 mg/ml solution for injection in pre-filled syringe

Never use EPHEDRINE AGUETTANT 3 mg/ ml, solution for injection in pre-filled syringe:

- if you are allergic to ephedrine or any of the other ingredients of this medicine listed in section 6
- in combination with other indirect sympathomimetic vasoconstrictors (such as pseudoephedrine and methylphenidate),
- in combination with alpha sympathomimetic drugs,
- in combination with irreversible MAOIs.

Warnings and precautions:

Special warnings

Caution is recommended in people who are likely to be particularly sensitive to the effects of ephedrine, particularly in the case of hyperthyroidism.

Particular attention is also required in people with cardiovascular diseases such as:

- cardiac ischaemia (chest pain),
- arrhythmia (irregular heart rate) or tachycardia (accelerated heart rate),
- vascular occlusions including arteriosclerosis (obstruction of the veins and arteries),
- hypertension (increased blood pressure)
- aneurysms (dilation of an artery wall),

Anginal pain may be worsened in people who have angina pectoris.

Particular attention must also be paid to people with diabetes, prostatic hypertrophy and closed-angle glaucoma.

Precautions for use

Ephedrine should be used with caution in people with a history of heart disease.

Talk to your doctor, pharmacist or nurse before taking EPHEDRINE AGUETTANT 3 mg/ml solution for injection in pre-filled syringe.

Other medicines and EPHEDRINE AGUETTANT 3 mg/1 ml, solution for injection in pre-filled syringe

Tell your doctor or pharmacist if you are taking, or have recently taken any other medicines, even medicines obtained without a prescription, particularly if this relates to:

- methylphenidate, used to treat attention and hyperactivity disorders,
- inhaled anaesthetic agents such as halothane,
- medicinal products used to treat depression,
- sibutramine, used as an appetite suppressant,
- linezolid, used for infections,
- ergot alkaloids, a drug class used as a vasoconstrictor or for its dopaminergic properties.

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

EPHEDRINE AGUETTANT 3 mg/ ml, solution for injection in pre-filled syringe with food and drink

Not applicable.

Pregnancy and breast-feeding

Pregnancy

If you are pregnant or breastfeeding, if you think you are pregnant or if you are planning to become pregnant, ask your doctor or pharmacist for advice before taking this medicine.

Ephedrine should be used during pregnancy only if necessary.

Breast-feeding

Given the method of administration of this medicinal product, breastfeeding is permitted.

Driving and using machines

Not applicable.

EPHEDRINE AGUETTANT 3 mg/ ml, solution for injection in pre-filled syringe contains sodium.

This medicine contains 33.9 mg sodium (main component of cooking/table salt) per 10 ml prefilled syringe. This is equivalent to 1.7% of the recommended maximum daily dietary intake of sodium for an adult.

3. HOW TO USE EPHEDRINE AGUETTANT 3 mg/ ml, solution for injection in pre-filled syringe

Dosage

Adults

The dose is 3 to 6 mg, repeated as needed every 5 to 10 minutes, and less than 150 mg/24 hours.

If it is ineffective, the choice of treatment should be reconsidered.

Use in children

The dose is 0.1 to 0.2 mg/kg every 4 to 6 hours.

If you feel that the effect of EPHEDRINE AGUETTANT 3 mg/1 ml, solution for injection in pre-filled syringe is too strong or too weak, talk to your doctor or your pharmacist.

Always take this medicine exactly as your doctor or pharmacist has told you to. In case of doubt, check with your doctor or pharmacist.

Method of administration

Injectable use. Intravenous infusion or IV bolus.

If you use more EPHEDRINE AGUETTANT 3 mg/ml solution for injection in pre-filled syringe than you should:

In the event of an overdose, nausea, vomiting, fever, paranoid psychoses, heart rhythm disturbances, hypertension (increased blood pressure), impaired ability to breathe, convulsions and coma may be observed.

If you forget to use EPHEDRINE AGUETTANT 3 mg/ ml, solution for injection in pre-filled syringe:

Not applicable.

If you stop using EPHEDRINE AGUETTANT 3 mg/ ml, solution for injection in pre-filled syringe:

Not applicable.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse for more information.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following side effects may occur:

Undetermined frequency: mental confusion, anxiety, depression, nervousness, irritability, insomnia, palpitations, hypertension (increase in blood pressure), tachycardia (accelerated heart rate), cardiac arrhythmia (heart rate disturbances), changes in coagulation parameters, hypersensitivity (allergy), tremors, closed-angle glaucoma crises, chest pain, reflex bradycardia, cardiac arrest, cerebral haemorrhaging, dyspnea (difficulty breathing), pulmonary oedema, urinary retention (difficulty urinating).

Reporting of 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. You can also report side effects directly via the national reporting system: Agence nationale de sécurité du médicament et des produits de santé [French National Agency for Medicines and Health Products Safety] (ANSM) and the network of Centres Régionaux de Pharmacovigilance [French Regional Pharmacovigilance Centres]. Website: www.signalement-sante.gouv.fr.

By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE EPHEDRINE AGUETTANT 3 mg/ ml, solution for injection in pre-filled syringe

Keep this medicine out of the sight and reach of children

Do not use this medicine after the expiry date which is stated on the syringe. The expiry date refers to the last day of that month.

Store the blister in the outer carton, protected from light.

Store below 30°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What EPHEDRINE AGUETTANT 3 mg/ ml, solution for injection in pre-filled syringe contains

The active substance is:

Ephedrine hydrochloride 3 mg
per 1 ml

The other ingredients are:

Sodium chloride, citric acid monohydrate, sodium citrate, hydrochloric acid or sodium hydroxide (for pH adjustment), water for injections.

What EPHEDRINE AGUETTANT 3 mg/ml solution for injection in pre-filled syringe looks like and contents of the pack

This medicinal product is a solution for injection in a 10 ml pre-filled syringe.

Box of 10.

Marketing Authorisation Holder

LABORATOIRE AGUETTANT
1 RUE ALEXANDER FLEMING
69007 LYON
FRANCE

Distributor

LABORATOIRE AGUETTANT
1 RUE ALEXANDER FLEMING
69007 LYON
FRANCE

Manufacturer

LABORATOIRE AGUETTANT
1 RUE ALEXANDER FLEMING
69007 LYON
FRANCE

Other

Detailed information on this medicine is available on the ANSM website (France).

Information intended for healthcare professionals only:

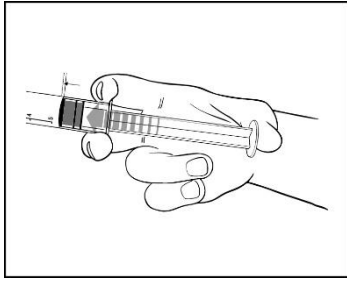
Be careful to strictly respect the instructions for use of the syringe.

The pre-filled syringe is for single patient only. After first use, the remaining product should be discarded.

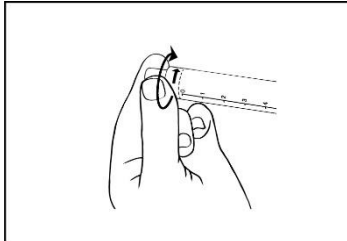
The content of un-opened and un-damaged blister is sterile, and must not be opened until use.

When handled using an aseptic method, EPHEDRINE AGUETTANT 3 mg/mL, solution for injection in pre-filled syringe can be placed on a sterile field.

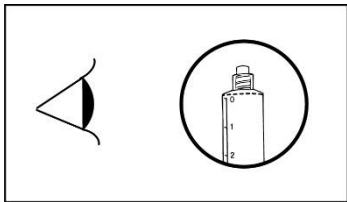
- 1) Withdraw the pre-filled syringe from the sterile blister.
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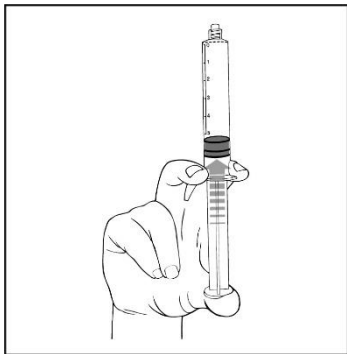
2) Push on the plunger to free the bung. The sterilisation process may have caused adhesion of the bung to the body of the syringe.



3) Twist off the end cap. Do not touch the exposed luer connection in order to avoid contamination.



4) Check the syringe seal tip has been completely removed.



5) Expel the air by gently pushing the plunger.

6) Connect the syringe to the IV access. Push the plunger slowly to inject the required volume.

7) After use, discard the syringe in accordance with local requirements in your facility.
