

**Package leaflet: Information for the user**

**PHENYLEPHRINE AGUETTANT 50 micrograms/ml solution for injection in pre-filled syringe**  
**Phenylephrine**

**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.
- 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 PHENYLEPHRINE AGUETTANT 50 micrograms/ml solution for injection in pre-filled syringe is and what it is used for
2. What you need to know before you are given PHENYLEPHRINE AGUETTANT 50 micrograms/ml solution for injection in pre-filled syringe
3. How PHENYLEPHRINE AGUETTANT 50 micrograms/ml solution for injection in pre-filled syringe is given
4. Possible side effects
5. How to store PHENYLEPHRINE AGUETTANT 50 micrograms/ml solution for injection in pre-filled syringe
6. Contents of the pack and other information

**1. What PHENYLEPHRINE AGUETTANT 50 micrograms/ml solution for injection in pre-filled syringe is and what it is used for**

This medicine belongs to a group of adrenergic and dopaminergic agents.

This medicinal product is used for:

- the treatment of hypotension during general anaesthesia and locoregional anaesthesia, whether spinal or epidural, and whether for surgical or obstetric procedures.
- the preventative treatment of hypotension during spinal anaesthesia for surgical or obstetric procedures.

**2. What you need to know before you are given PHENYLEPHRINE AGUETTANT 50 micrograms/ml solution for injection in pre-filled syringe**

**Never use PHENYLEPHRINE AGUETTANT 50 micrograms/ml solution for injection in pre-filled syringe:**

- if you are allergic to phenylephrine hydrochloride or any of the other ingredients of this medicine (listed in section 6);
- if you suffer from severe high blood pressure, or peripheral vascular disease (poor blood circulation);
- if you are taking a Monoamine Oxydase inhibitor (MAOI) (or within 2 weeks of their withdrawal), that is used to treat depression (such as iproniazide, nialamide);

- if you suffer from severe overactive thyroid gland (hyperthyroidism).

### **Warnings and precautions**

Talk to your doctor or pharmacist before using PHENYLEPHRINE AGUETTANT 50 micrograms/ml solution for injection in pre-filled syringe. Monitor arterial and venous blood pressure during treatment.

Caution is recommended:

- if you are elderly;
- if you are diabetic;
- if you suffer from arterial hypertension;
- if you have an overactive thyroid gland (uncontrolled hyperthyroidism);
- if you have blood vessel disease, such as arteriosclerosis (hardening and thickening of the walls of the blood vessels);
- if you have a poor blood circulation in the brain;
- if you suffer from heart disease including chronic heart conditions, peripheral vascular insufficiency, heart rhythm disorders, tachycardia (high heart rate), bradycardia (low heart rate), partial heart block, angina pectoris;
- if you suffer from a closed angle glaucoma (a rare eye disease).

In patients with serious heart failure, phenylephrine may worsen the heart failure as a consequence of blood vessel constriction.

The blood pressure in your arteries will be monitored during treatment. If you have heart disease, additional monitoring of vital functions will be performed.

### **Children**

This medicine is not recommended for use in children due to insufficient data on efficacy, safety and dosage recommendations.

### **Other medicines and PHENYLEPHRINE AGUETTANT 50 micrograms/ml solution for injection in pre-filled syringe**

Tell your doctor if you are using, have recently used or might use any other medicines, such as:

- certain antidepressants (iproniazid, nialamide, moclobenide, toloxatone, imipramine, milnacipran or venlafaxine);
- medicine used to treat infections (linezolid);
- certain medicines used to treat migraine (dihydroergotamine, ergotamine, methylergometrine, methysergide);
- certain medicines used to treat Parkinson disease (bromocriptine, lisuride, pergolide);
- medicine used to inhibit the production of an hormone responsible of lactation (cabergoline);
- anaesthetics that are inhaled (desflurane, enflurane, halothane, isoflurane, methoxyflurane, sevoflurane);
- medicine used as an appetite suppressant (sibutramine);
- medicine used to treat high blood pressure (guanethidine);
- medicines used to treat heart failure and certain irregular heartbeats (cardiac glycosides);
- medicine used to treat abnormal heart rhythm (quinidine);
- medicine used during labour (oxytocin).

**PHENYLEPHRINE AGUETTANT, 50 micrograms/ml solution for injection in pre-filled syringe, with food and drinks**

Not applicable.

**Pregnancy and breast-feeding**

The safety of this medicine during pregnancy and breast-feeding has not been established, but the use of Phenylephrine Injection is possible during pregnancy in accordance with the indications.

Use of this medicine during breast-feeding is not recommended. However, in the event of a single administration during childbirth, breast-feeding is possible.

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.

**Driving and using machines**

This medicinal product is not compatible with driving a vehicle or operating machinery.

**PHENYLEPHRINE AGUETTANT 50 micrograms/ml solution for injection in pre-filled syringe contains sodium**

This medicine contains 37.2 mg sodium (main component of cooking/table salt) in each syringe. This is equivalent to 1.9% of the recommended maximum daily dietary intake of sodium for an adult.

**3. How PHENYLEPHRINE AGUETTANT 50 micrograms/ml solution for injection in pre-filled syringe is given**

The administration will be performed by a healthcare professional with appropriate training and relevant experience, who will decide the correct dosage for you and when and how the injection should be administered.

**The recommended doses are:**

**Use in Adults**

Your doctor will determine the dose to be administered, and may repeat or adjust it until the desired effect is attained.

**Use in patients with impaired renal function** (kidneys not functioning well)

Lower doses of phenylephrine may be needed in patients with impaired renal function.

**Use in patients with impaired liver function** (liver not functioning well)

Higher doses of phenylephrine may be needed in patients with cirrhosis of the liver.

**Use in older people**

Treatment in older people should be carried out with care.

**Use in children**

This medicine is not recommended for use in children due to insufficient data on efficacy, safety and dosage recommendations..

**If you have been given more PHENYLEPHRINE AGUETTANT 50 micrograms/ml solution for injection in pre-filled syringe than you should:**

You may have the following symptoms: palpitation, cardiac rhythm disorders (tachycardia, cardiac arrhythmias).

**If you forget to use more PHENYLEPHRINE AGUETTANT 50 micrograms/ml solution for injection in pre-filled syringe**

Not applicable.

**If you stop using PHENYLEPHRINE AGUETTANT 50 micrograms/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

#### **4. Possible side effects**

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

**Some side effects may be serious (frequencies are not known). Tell your doctor straight away if you get any of the following:**

- chest pain or pain due to the angina,
- irregular heartbeat,
- feeling the heart pumping in the chest,
- bleeding in the brain (speech disorder, dizziness, paralysis of one side of the body);
- psychosis (loosing contact with reality),

Other side effects may include (frequencies are not known):

- reaction of hypersensitivity (allergy),
- excessive dilation of the pupils,
- increased pressure in the eye (aggravation of glaucoma),
- excitability (excessive sensitivity of an organ or body part),
- agitation (restlessness),
- anxiety,
- confusion,
- headache;
- nervousness,
- insomnia (difficulty falling or staying asleep),
- shaking (tremor),
- burning of the skin,
- prickling of the skin,
- itching or tingling skin sensation (paresthesia),
- slow or high heart rate,
- high blood pressure,
- difficulty in breathing,
- fluids in the lung;
- nausea,
- vomiting;
- sweating,

- pallor or skin blanching (pale colour of the skin),
- goose flesh,
- tissue damage at the site of the injection;
- muscle weakness;
- difficulty in passing urine or urine retention

## **5. How to store PHENYLEPHRINE AGUETTANT 50 micrograms/ml solution for injection in pre-filled syringe**

Keep this medicine out of the sight and reach of children.

You should not be given this medicine after the expiry date which is stated on the syringe, the blister and the carton. The expiry date refers to the last day of that month. Your doctor or nurse will check this.

Keep the syringe in its unopened blister, in the outer box, in order to protect from light. Store below 30°C.

Any syringe, even partially used, should be discarded appropriately after use.

Do not use this medicine if you notice visible signs of deterioration.

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 PHENYLEPHRINE AGUETTANT 50 micrograms/ml solution for injection in pre-filled syringe contains**

The active ingredient is phenylephrine (as hydrochloride).

- Each ml of solution for injection contains phenylephrine hydrochloride, equivalent to 50 micrograms phenylephrine.
- Each 10 ml pre-filled syringe contains phenylephrine hydrochloride, equivalent to 500 micrograms phenylephrine.
- The other ingredients are sodium chloride, sodium citrate dihydrate, citric acid monohydrate, sodium hydroxide, and water for injections.

### **What PHENYLEPHRINE AGUETTANT 50 micrograms/ml solution for injection in pre-filled syringe looks like and contents of the pack**

This medicinal product is a clear colourless solution for injection, in a 10 ml (polypropylene) pre-filled syringe for single use.

Boxes of 10 pre-filled syringes.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer**

LABORATOIRE AGUETTANT

1, rue Alexander Fleming  
69007 LYON  
France

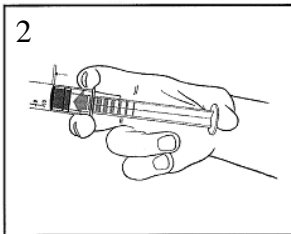
**This leaflet was last revised in .**

The following information is intended for healthcare professionals only:

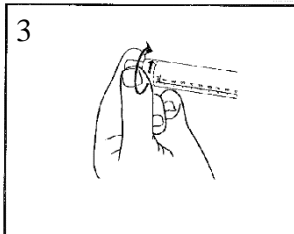
**Please prepare the syringe carefully as follows**

The pre-filled syringe is for single patient only. Discard syringe after use.  
The content of un-opened and un-damaged blister is sterile, and must not be opened until use.  
When handled using an aseptic method, Phenylephrine 50 micrograms/ml, solution for injection in pre-filled syringe can be placed on a sterile field.

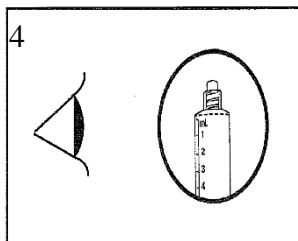
1) Withdraw the pre-filled syringe from the sterile blister.



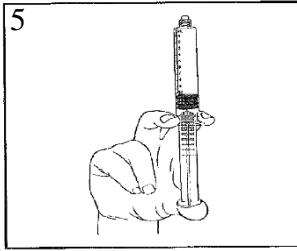
2) Push on the plunger to free the bung. The sterilisation process may have caused adhesion of the bung to the body of the syringe.



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



4) Check the syringe seal tip has been completely removed. If not, replace the cap and twist again



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, dispose of the syringe according to the practices in force in your facility.