Package leaflet: Information for the user

ATROPINE SULFATE AGUETTANT 0.2 mg/ml

Solution for injection in pre-filled syringe

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.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

The name of this medicinal product is ATROPINE SULFATE AGUETTANT 0.2 mg/ml solution for injection in pre-filled syringe, but will be referred as ATROPINE SULFATE AGUETTANT throughout the whole leaflet.

What is in this leaflet:

1. What ATROPINE SULFATE AGUETTANT is and what it is used for

Atropine belongs to a group of medicines known as anticholinergics. An anticholinergic is a substance that blocks the neurotransmitter acetylcholine in the central and peripheral nervous system. It is used in emergency situations when the heart beats too slowly, as an antidote to for example organophosphate insecticide or nerve gas poisoning and in mushroom poisoning.
It can be used as part of the premedication before general anaesthesia. It can also be used to prevent side effects of other drugs which are used to reverse the effects of muscle relaxants after surgery.
ATROPINE SULFATE AGUETTANT 0.2 mg/ml solution for injection in pre-filled syringe is used to treat adults only.

2. What you need to know before you use ATROPINE SULFATE AGUETTANT

Do not use ATROPINE SULFATE AGUETTANT if you:
- are allergic (hypersensitive) to atropine or any of the other ingredients of this medicine (listed in section 6)
- have urinary difficulties,
- have elevated pressure in your eye (glaucoma),
- have oesophagus disease (achalasia of oesophagus), a blockage in your intestine (paralytic ileus), or acute form of colonic distension (toxic megacolon).

These contraindications do not apply in case of life-threatening emergencies.

Warnings and precautions
Talk to your doctor before using ATROPINE SULFATE AGUETTANT if you have:
- hyperthyroidism,
- prostatic disease,
- heart failure,
- liver or kidney disease,
- some cardiac diseases,
- stomach disease, such as pyloric narrowing,
- chronic bronchitis,
- fever,
- myasthenia gravis (severe muscle weakness),
- heartburn (reflux),
- Or if you are elderly.

Other medicines and ATROPINE SULFATE AGUETTANT
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines:
- tricyclic antidepressants,
- some antihistamines,
- medicines for Parkinson's disease,
- phenothiazine, clozapine or neuroleptic drugs (for mental illness),
- quinidine or disopyramide (for heart disease),
- antispasmodic medications (for irritable bowel syndrome).

Pregnancy and breast-feeding

Pregnancy
Limited data from the use of atropine in pregnant women indicate no adverse effects on pregnancy or on the health of the fetus. Atropine crosses the placenta. Intravenous administration of atropine during pregnancy or at term may cause a faster heart rate in the fetus and the mother. This medicine should only be administered during pregnancy after careful consideration of the benefits and risks of the treatment.

Breast-feeding
Small amounts of atropine may pass into breast milk and may have effects on the infant. Atropine may inhibit the production of breast milk. Your doctor will consider the benefit of breast-feeding against the benefit of the treatment. Breast-feeding should be discontinued if the decision to use the treatment is maintained. However, if it is decided during treatment to continue breast-feeding, your doctor will perform extra examinations on the infant.

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.

Driving and using machines
Atropine injection may cause confusion or blurred vision. You should not drive or operate machinery after receiving an injection.

ATROPINE SULFATE AGUETTANT contains sodium
This medicinal product contains less than 1 mmol sodium (23 mg) per syringe, i.e. essentially "sodium-free."

3. How to use ATROPINE SULFATE AGUETTANT

Your doctor will decide the correct dosage for you and how and when the injection will be given.

The usual dosages are:

As premedication before anaesthesia
Adults: 0.3-0.6 mg IV just before induction of anaesthesia or 0.3-0.6 mg IM, 30 to 60 minutes before the anaesthesia.

To reverse effects of muscle relaxants
Adults: 0.6-1.2 mg intravenously (IV) with neostigmine.

In low heartbeat, heart block or cardiac arrest
Adults:

- Sinus bradycardia (low heartbeat): 0.5 mg IV, every 2-5 minutes until the desired heart rate is achieved.
- AV block (Block the transmission of the contraction between the atrium and the ventricle): 0.5 mg IV, every 3-5 minutes (maximum 3 mg)

As an antidote to organophosphorus poisoning (insecticides, or nerve gas), to anticholinesterases and in muscarinic mushroom poisoning:
Adults: 0,5-2 mg depending on the patient's features and response, can be repeated after 5 minutes and subsequently as required.

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

This injection will be given to you by a doctor or nurse, it is unlikely that you will be given too much atropine. If you think you have been given too much atropine, you feel your heart beating very fast, you are breathing quickly, have a high temperature, feel restless, confused, have hallucinations, or lose co-ordination you must tell the person giving you the injection.

4. Possible side effects

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

The side effects depend on the dose you are given and usually disappear when the treatment is discontinued.

Rarely an allergic reaction may develop. This may cause skin rashes, severe itching, peeling of the skin, swelling of the face (especially around the lips and eyes), tightening of the throat and difficulty breathing or swallowing, fever, dehydration, shock and fainting. These are all very serious side effects. Tell your doctor immediately if you experience any of these side effects. You may need urgent medical attention.

Very common side effects (may affect more than 1 in 10 people)

- visual disturbances (widening of the pupils, difficulty focussing, blurred vision, inability to tolerate light),
- reduced bronchial secretion,
- dry mouth (difficulty in swallowing and talking, feeling thirsty),
- constipation and heartburn (reflux),
- reduced secretion of gastric acid,
- loss of taste,
- nausea,
- vomiting,

- bloated feeling,
- lack of sweating,
- skin dryness,
- hives,
- rash.

Common side effects (may affect up to 1 in 10 people)
- excitement (especially with higher dosages),
- loss of coordination (especially with higher dosages),
- confusion (especially with higher dosages),
- hallucinations (especially with higher dosages),
- overheated body,
- certain heart conditions (rapid heart beat, irregular heart beat, temporary further slowing down of heart beat),
- flushing,
- difficulty in passing urine.

Uncommon side effects (may affect up to 1 in 100 people)
- psychotic reactions.

Rare side effects (may affect up to 1 in 1,000 people)
- allergic reactions,
- fits (seizures),
- drowsiness.

Very rare side effects (may affect up to 1 in 10,000 people)
- severe hypersensitivity reaction,
- irregular heart beat, including ventricular fibrillation,
- chest pain,
- spike in blood pressure.

Not known (frequency cannot be estimated from the available data)
- headache,
- restlessness,
- unsteady walking and balance problems,
- sleeplessness.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system:
HPRA Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
e-mail: medsafety@hpra.ie
By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store ATROPINE SULFATE AGUETTANT

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 carton, the syringe and blister. The expiry date refers to the last day of that month.
This medicinal product does not require any special storage conditions.
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 ATROPINE SULFATE AGUETTANT contains

- The active substance is atropine sulfate:
  Each ml of solution for injection contains 0.2 mg atropine sulfate monohydrate, equivalent to 0.17 mg atropine
  Each 5 ml syringe contains 1 mg atropine sulfate monohydrate, equivalent to 0.83 mg atropine.,
- The other ingredients are: sodium chloride, concentrated hydrochloric acid (for pH adjustment), water for injections.

What ATROPINE SULFATE AGUETTANT looks like and contents of the pack.
This medicinal product is a clear and colourless solution for injection in a sterile 5 ml polypropylene pre-filled syringe.
Boxes of 1, 5, 10, 12 and 20 syringes.
Not all pack sizes may be marketed.

Marketing Authorisation Holder
Laboratoire AGUETTANT
1, rue Alexander Fleming
69007 LYON
FRANCE

Manufacturer
Laboratoire AGUETTANT
1, rue Alexander Fleming
69007 LYON
FRANCE

Laboratoire AGUETTANT
Lieu-dit “Chantecaille”
07340 CHAMPAGNE
France

Distributor
Aguettant Ltd
N°1 Farleigh House - Flax Bourton
Bristol BS48 1UR
United Kingdom

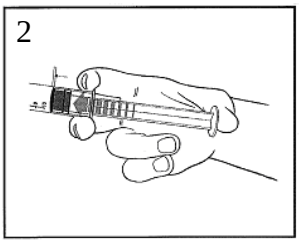
This leaflet was last revised in 12/2021.

Detailed information on this medicinal product is available on the web site of the Health Products Regulatory Authority.

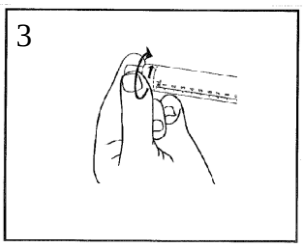
The following information is intended for healthcare professionals only:

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 used.

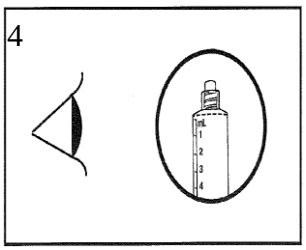
The product should be inspected visually for particles and discoloration prior to administration. Only clear colourless solution free from particles or precipitates should be used.
The product should not be used if the tamper evident seal on syringe (plastic cover to the end cap) is broken.
The external surface of syringe is sterile until blister is opened.
1) Withdraw the pre-filled syringe from the sterile blister.



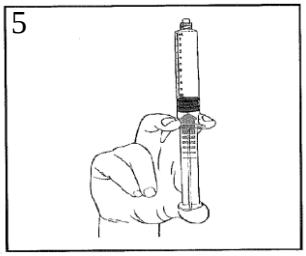
2) Push on the plunger to free the bung.



3) Twist off the end cap to break the seal.



4) Check the syringe seal (plastic cover to the end cap and seal under end cap) 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 vascular access device or needle. Push the plunger to inject the required volume.
The needle gauge appropriate for use with the syringe are 23 to 20 gauge for IV administration and 23 to 21 gauge for IM administration.