Package leaflet: Information for the user

Atropin Abboxia 0,5 mg/ml solution for injection
Atropin Abboxia 1 mg/ml solution for injection

atropine sulphate

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 nurse.
- 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 Atropin Abboxia is and what it is used for

Atropin Abboxia belongs to a group of medicines which are called anticholinergics. Atropine sulphate, the active substance in Atropin Abboxia, temporarily blocks some nerve endings. This decreases glands secreting, makes some muscles (such as in the gut) relax and speeds up the heart. Atropin Abboxia is used for:
- relaxation of muscles in the gastro-intestinal tract during cramps
- to reduce saliva, fluid in the lungs and/or gastric juice
- to treat a slow heartbeat
- as medication during surgery.

2. What you need to know before you use Atropin Abboxia

Do not use Atropin Abboxia
- if you are allergic to atropine sulphate or any of the other ingredients of this medicine (listed in section 6)
- if you have troubles passing urine (i.e. if you are a man and have an enlarged prostate)
- if you have increased pressure in the eye (glaucoma)
- if you have blockage in the intestines or paralysis of the bowel
- if you suffer from severe inflammation of the colon (ulcerative colitis) or complication of colonic inflammation

These contraindications do not apply in the event of life-threatening situations.

Warnings and precautions
Talk to your doctor before your are given Atropin Abboxia.
Special caution should be taken in patients with:
- certain heart conditions (tachyarrhythmias, heart failure or coronary heart disease)
- high blood pressure
- bowel or stomach problems, such as narrowing of the opening between the stomach and the small intestine (pyloric stenosis), stomach ulcer, heartburn or reflux, diarrhoea or infection, hiatus hernia (when a part of the stomach prolapses through the diaphragm)

- raised temperature
- liver or kidney problems
- an overactive thyroid gland
- symptoms resulting from damage to the nerves that regulate blood pressure, heart rate, bowel and bladder emptying, digestion and other body function (autonomic neuropathy)
- surgically created artificial opening in the small or large intestine (ileostomy or a colostomy)
- chronic lung disease
- severe muscle weakness (myasthenia gravis)

Children
Atropin Abboxia should be used with caution in children as they are more sensitive to the effects of the product.

Elderly
Atropin Abboxia should be used with caution in elderly patients as they are more sensitive to the effects of the product. Dose reduction may be necessary in elderly.

Other medicines and Atropin Abboxia
Tell your doctor if you are taking, have recently taken or might take any other medicines.

This includes
- tricyclic antidepressants (for treatment of depression)
- antispasmodics (used for relieving intestinal pain and muscles spasms or cramps)
- amantadin or similar medicinal products (for treatment of Parkinsons disease)
- certain antihistamines (for treatment of hay fever and allergies)
- fentiazines (for treatment of anxiety or more severe mental diseases)
- disopyramide and quinidine (medicinal products used for controlling the heart rhytm).

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 for advice before taking this medicine.

Pregnancy
Data from a limited number of exposed pregnancies do not indicate any adverse effects of atropine on pregnancy or foetus/newborn health. Atropin crosses the placental barrier. Intravenous administration of atropine during pregnancy or at term may cause tachycardia (fast heart rate) in the foetus and the mother. Atropin Abboxia should only be used during pregnancy after careful consideration of the benefits and risks of treatment.

Breastfeeding
Small amounts of atropine may pass into breast milk. Infants have an increased sensitivity to the anticholinergic effects of atropine. Atropine may inhibit lactation, especially with repeated use. 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

Driving and using machines
A common side effect of this medicinal product is impaired near-sightedness and accommodation paresis which should be considered when driving.

Atropin Abboxia contains sodium
This medicinal product contains less than 1 mmol (23 mg) sodium per ml solution of injection, i.e it is almost ”sodium free”.

3. How to use Atropin Abboxia

Atropin Abboxia is given as an injection by a doctor or a by a specially trained nurse. The injection could be given under the skin or directly into the blood (in a vein). The doctor will decide which dose that is appropriate for you.

If you have been given more Atropin Abboxia than you should
It is unlikely that you will be given more than you should of this medicinal product as it is only given by a doctor or a nurse. If you suspect that you have been given more than you should then you should talk immediately to your doctor or nurse.

Overdosing of Atropin Abboxia may result in dry mucous membranes or skin, thirst, face rush, irregular heartbeat, fast breathing, dilution of the pupils, blurred vision, fever, difficulties in passing urine, restlessness, cramps, excitation, hallucinations (to see or hear things that are not real), unconsciousness, increased blood pressure as well as circulatory failure in severe cases.

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

4. Possible side effects

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

An allergic reaction may occur in rare cases. It may cause skin rash, severe itch, scaling of skin, swollen face (especially around lips and eyes), swollen throat and difficulties in breathing or swallowing, fever, dehydration, chock, and fainting. All these side effects are very serious. **Immediately** tell your doctor if you get these side effects.

The most common side effect is mouth dryness and it is experienced by most patients. Mouth dryness gives a risk of tooth- and mucosa membrane injuries at long term use.

The side effects depend on the dose you are given.

<u>Very common side effects (may occur in more than 1 in 10 people)</u>
- widening of the pupils, blurred vision, inability to tolerate light
- constipation
- heart burn (reflux)
- nausea
- vomiting
- bloating
- reduced bronchial secretion
- lack of sweating
- rash
- hives

<u>Common side effects (may occur in 1 of 10 users)</u>
- rapid heart beat
- excitement
- confusion
- hallucinations (at high doses)
- difficulty focusing eyes
- dry mouth
- urination problems
- difficulties in passing urine
- irregular heart beat
- overheated body
- flushing

Uncommon side effects (may occur 1 in 100 users)
- psychotic reactions

Rare side effects (may occur in up to 1 of 1,000 users)
- allergic reactions
- fits (seizures)
- drowsiness

Very rare side effects (may occur 1 in 10,000 users)
- irregular heart beat, including ventricular fibrillation
- chest pain
- spike in blood pressure
- severe hypersensitivity reaction

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

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 Atropin Abboxia

No special storage conditions.

After opening: the product should be used immediately.

After dilution: Chemical and physical in-use stability has been demonstrated for up to 48 hours at room temperature.
If handling does not preclude microbiological contamination, the diluted product should be used immediately.

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 after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater. 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 Atropin Abboxia contains

- The active substance is atropin sulphate.
- The other ingredients are sulphuric acid (for pH adjustment), sodium chloride and water for injections.

What Atropin Abboxia looks like and contents of the pack
Glass ampoule: 5 x 1 ml, 10 x 1 ml, 20 x 1 ml, 50 x 1 ml, 100 x 1 ml

Marketing Authorisation Holder

Abboxia AB
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431 21 Mölndal
Sweden

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This leaflet was last revised in 2026-03-06

The following information is intended for healthcare professionals only:

Dilution
Atropin Abboxia may be diluted using 9 mg/ml (0,9 %) sodium chloride or 50 mg/ml (5 %) glucose and stored in polypropylene (PP) syringes.

The following diluted concentration is applicable:
- 0,1 mg/ml (based on 0,5 mg/ml and 1 mg/ml)

Storage conditions
No special storage conditions.

After opening: the product should be used immediately.

After dilution: Chemical and physical in-use stability has been demonstrated for up to 48 hours at room temperature.
If handling does not preclude microbiological contamination, the diluted product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user.