SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml solution for injection contains 0,5 mg atropine sulphate.
1 ampoule á 1 ml contains 0,5 mg atropine sulphate.

1 ml solution for injection contains 1 mg atropine sulphate.
1 ampoule á 1 ml contains 1 mg atropine sulphate.

Excipient with known effect
1 ml solution for injection contains 3,5 mg sodium

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection

Clear, colourless solution

pH: 2,8 – 4,5
Osmolality: 280-320 mOsm/kg

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Atropin Abboxia is indicated in children and adults for:
• Spastic contractions in the gastrointestinal tract
• Hypersecretion of saliva, bronchial fluid and/or gastric acid.
• Bradycardia.
• Per operative medication.

4.2 Posology and method of administration

Posology

Adults
Spastic contractions in the gastrointestinal tract, hypersecretion:
Administered in optimal effective dose which is titrated individually and with moderate mouth dryness as a sign of achievement of an optimal dose.
Bradycardia: 0,5–1 mg intravenously.
Per operative medication in adults: 0,5 mg subcutaneously.

Pediatric population
Per operative medication to children:

3–10 kg	0,10–0,15 mg
10–12 kg	0,15 mg
12–15 kg	0,20 mg
15–17 kg	0,25 mg
17–20 kg	0,30 mg
20–30 kg	0,35 mg
30–50 kg	0,40–0,50 mg

Subcutaneous injection should be given 1 hour before surgery. In case of narrow timelines, an emergency dose 0,75 of the recommended subcutaneous dose may be injected intravenously 10-15 minutes before initiation of anesthesia. The effect though becomes worse.

Elderly
Dose reduction may be necessary in elderly.

Method of administration
Atropin Abboxia 0,5 mg/ml is used for both intravenous and subcutaneous administration.
Atropin Abboxia 1 mg/ml is used for intravenous administration.

4.3 Contraindications

- Hypersensitivity to atropine sulphate or to any of the excipients listed in section 6.1
- Bladder outblow obstruction (i.e., prostate enlargement)
- Angle-closure glaucoma or a narrow angle between the iris and the cornea
- Gastrointestinal obstruction or paralytic ileus
- Severe ulcerative colitis or toxic megacolon

Contraindications do not apply when atropine is used in life-threatening situations (e.g., bradyarrhythmia, poisoning).

4.4 Special warnings and precautions for use

- Atropine blocks vagal inhibition of the SA nodal pacemaker and should thus be used with caution in patients with tachyarrhythmias, congestive heart failure or coronary heart disease.
- Atropine should be used with caution in patients with hyperthyroidism, hepatic or renal disease or hypertension and in patients with high temperature or fever since it reduces the ability to sweat, thus increasing the risk of hyperthermia.
- Parenterally administered atropine should be used cautiously in patients with chronic pulmonary disease since a reduction in bronchial secretions may lead to formation of bronchial plugs.
- Antimuscarinics should be used with extreme caution in patients with autonomic neuropathy. Atropine should not be given to patients with myasthenia gravis except to reduce adverse muscarinic effects of an anticholinesterase.
- Atropine decreases gastric motility, relax the lower oesophageal sphincter and may delay gastric emptying; it should therefore be used with caution in patients with pyloric stenosis, gastric ulcer, oesophageal reflux or hiatus hernia associated with reflux oesophagitis, diarrhoea or gastrointestinal infection.
- Atropine should be used with caution in patients with ileostomy or colostomy.
- During inhalation anaesthesia (especially with halothane), anticholinergics may cause cardiac arrhythmia.

Antimuscarinic agents should be used with caution in children and elderly, as they are more susceptible to the anticholinergic effects of atropine. Dose reduction may be necessary in elderly.

This medicinal product contains less than 1 mmol (23 mg) sodium per ml solution for injection, i.e. almost “sodium free”.

4.5 Interaction with other medicinal products and other forms of interaction

The effects of atropine may be enhanced by concomitant administration of other medicinal products with anticholinergic effect i.e., tricyclic antidepressants, antispasmodics, anti-Parkinson medicines (i.e. amantadine), some antihistamines, fentiazines, antiarrhythmics class Ia (i.e. disopyramide and quinidine).

4.6 Fertility, pregnancy and lactation

Pregnancy
Animal studies did not indicate direct or indirect harmful effects with respect to reproductive toxicity (see section 5.3).

Data from a limited number of exposed pregnancies do not indicate any adverse effects of atropine on pregnancy or foetus/newborn health.Studies of the pharmacokinetics of atropine in mother and foetus in late pregnancy indicated that atropine rapidly crosses the placental barrier. Intravenous administration of atropine during pregnancy or at term may cause tachycardia in the foetus and the mother.

Atropin Abboxia should not be used during pregnancy unless absolutely necessary.

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. A decision must be made whether to discontinue breastfeeding or to discontinue/abstain from treatment taking into account the benefit of breastfeeding for the child and the benefit of treatment for the woman. If it is decided to continue breastfeeding during treatment, the child should be monitored for anticholinergic effects.

Fertility
There are no data on effect of atropine sulphate on fertility in humans. Atropine sulphate reduced fertility in male rats, presumably as a consequence of an inhibitory effect on the transport of sperm and semen during the process of emission.

4.7 Effects on ability to drive and use machines

Atropin Abboxia has a major influence on the ability to drive and use machines. A common side effect of this medicinal product is impaired near-sightedness and accommodation paresis which should be considered when driving.

4.8 Undesirable effects

Mouth dryness is the most common side effect at therapeutic doses and most patients experience this. The side effects of atropine to a large extent depends on the pharmacological effects of atropine and which are dose dependent.

The adverse reactions are classified according to frequency of occurrence as follows:
Very common (≥1/10); common (≥1/100, <1/10); uncommon (≥1/1 000, <1/100); rare (≥1/10 000,
<1/1 000); very rare (<1/10 000); not known (cannot be estimated from the available data).

System organ class	Very common (≥1/10)	Common (≥1/100, <1/10)	Uncommon (≥1/1,000, <1/100)	Rare (≥1/10,000, <1/1,000)	Very rare (<1/10,000)	Not known (frequency cannot be estimated from the available data)
Psychiatric disorders		Excitation, disorientation and hallucinations (at high doses)				
Nervous system disorders		Mouth dryness, hyperthermia	Psychotic reactions	Seizures, drowsiness		Ataxia, headache
Eye disorders	Mydriasis, blurred vision, photophobia	Accommodation paresis				
Cardiac disorders		Increased heart rate, cardiac arrythmia			Atrial arrhythmias, ventricular fibrillation, hypertensive crisis	
Renal and urinary disorders		Micturition problems, inhibition of the parasympathetic control of the urinary bladder, urinary retention				
Gastrointestinal disorders	Parasympathetic inhibition of the GI tract (constipation, reflux, nausea, vomiting, bloating					
Immune reactions				Allergic reactions	Anaphylaxis	
Respiratory, thoracic and mediastinal disorders	Reduced bronchial secretion					

System organ class	Very common (≥1/10)	Common (≥1/100, <1/10)	Uncommon (≥1/1,000, <1/100)	Rare (≥1/10,000, <1/1,000)	Very rare (<1/10,000)	Not known (frequency cannot be estimated from the available data)
Skin and subcutaneous tissue disorders	Anhidrosis, rash, urticaria					
Vascular disorders		Flushing				

Mouth dryness implies a risk of tooth- and mucous membrane injuries at long term use.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system listed in Appendix V.

4.9 Overdose

Symptoms of overdose
Dryness in mucous membranes and skin, thirst. Face rush. Tachycardia and tachypnea. Mydriasis, blurred vision. Fever. Urine retention. Motor anxiety, potential cramps, excitation, hallucinations. Unconsciousness. Blood pressure increase. Circulatory failure in severe cases.

Treatment of overdose
If appropriate at oral intake, gastric emptying, charcoal, potential laxative. Physostigmine 1-2 (-3) mg administered slowly i.v. (2 minutes), children 0,02-0,04 mg/kg, towards central anticholinergic symptoms. Titrated to an effective dose (atropine available for reversal of potential overdose symptoms). The effective dose may be repeated every 30-60 minutes. Alternatively, physostigmine may be administered as a continuous infusion 1-3 mg/hour. At expressed excitation and cramps, diazepam 10 mg i.v., children 0,1-0,2 mg/kg (not morphine or long-term acting barbiturates). Catheterization of the bladder. Metoprolol (alternatively atenolol) is administered slowly i.v for tachycardia which is giving symptoms. Dark and quiet room. Eyedrops which contracts the pupils may be given at troublesome mydriasis. Symptomatic treatment.

Toxicity
Lethal atropine poisoning is rare. Lethal dose for children is assumed to be 10-20 mg. Lethal dose for adults is assumed to be over 200 mg and in one case 1 g resulted only in moderate to severe intoxication. Small children are especially sensitive. Approx. 6 mg to a 3-year-old gave moderate intoxication. 3 drops of a 1 % solution (= 1,5 mg) in each eye for 24 hours resulted in severe intoxication in a 2-year-old child. 1 drop in each eye 2 times daily of a 25 % solution for 2 days (= 100 mg) resulted in severe intoxication in a 6-year-old child.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: anticholinergics with tertiary amino group, ATC code: A03BA01

Atropine is a tertiary amine. Atropine has a relaxing effect on smooth muscles. It inhibits motility and prohibits spastic contractions in the gastrointestinal tract. Atropine inhibits secretion mainly on saliva, bronchial fluid and gastric acid. It also decreases secretion from sweat glands while the amount of bile, urine and milk is not affected. The heart frequency is increased by atropine due to inhibiting effect on vagus. Atropine also has effect on the central nervous system at higher doses.

5.2 Pharmacokinetic properties

-

5.3 Preclinical safety data

Effects in preclinical studies were observed only at exposures considered sufficiently in excess of the maximum human exposure indicating little relevance to clinical use. Atropine sulphate reduced fertility in male rats, presumably as a consequence of an inhibitory effect on the transport of sperm and semen during the process of emission.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sulphuric acid (pH adjustment)
Sodium chloride
Water for injections

6.2 Incompatibilities

This medicinal product must not be mixed with other medicinal products except those mentioned in section 6.6.

6.3 Shelf life

3 years

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.
From a microbiological point of view, unless the method of opening, dilution, or reconstitution precludes the risk of microbial contamination, the product should be used immediately.
If not used immediately, in-use storage times and conditions are the responsibility of the user.

6.4 Special precautions for storage

No special storage conditions.

For storage conditions after dilution of the medicinal product, see section 6.3.

6.5 Nature and contents of container

Glass ampoule: 5 x 1 ml, 10 x 1ml, 20 x 1 ml, 50 x 1 ml, 100 x 1 ml.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

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)

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Abboxia AB
Box 50
431 21 Mölndal

8. MARKETING AUTHORISATION NUMBER(S)

[To be completed nationally]

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

[To be completed nationally]

10. DATE OF REVISION OF THE TEXT

2026-03-06