

## Atropine sulfate 0.25 mg/ml, 0.50mg/ml solution for injection

### What is Atropine sulfate and what is it used for?

Atropine is a belladonna alkaloid belonging to the group of anticholinergics. These are substances that counteract the action of the body's own substance acetylcholine. Acetylcholine is important for the functioning of the so-called autonomic nervous system that regulates many internal organs such as the heart, blood circulation, lungs, and gastrointestinal tract.

### Indications

- Preparation for or during surgery (to reduce salivation and secretion in the airways and to stimulate one of the cranial nerves (vagus nerve)).
- As an antidote after administration of a too high dose of substances that reduce the activity of the enzyme cholinesterase (cholinesterase inhibitors) and other substances that stimulate the autonomic nervous system (parasymphathomimetics).
- To treat a slow heart rate caused by a poorly functioning node in the heart where the impulses for contraction are generated (sinus bradycardia) in the acute phase of a heart attack.

### When should you not use this medicine or take special precautions?

When should you not use this medicine?

- You are allergic to any of the ingredients in this medicine.
- You have prostate enlargement (prostatic hypertrophy).
- You have a condition where the gastrointestinal tract is obstructed (gastrointestinal obstruction) (e.g. due to pyloric stenosis).
- You have bowel obstruction due to paralysis of the intestinal muscle (paralytic ileus).
- You have the type of increased eye pressure that is a result of poor drainage of the eye fluid.

Close-angle glaucoma or untreated open-angle glaucoma.

### When should you be extra cautious with this medication?

You should be extra cautious when using Atropine sulfate in:

- Children and the elderly, • Diarrhea, • Fever or high ambient temperature, • Liver or kidney dysfunction, • Infection of the gastrointestinal tract, • Damage to the part of the nervous system that controls unconscious functions (autonomic neuropathy), • Heart disease, unstable status of the heart and blood vessels (cardiovascular status) in acute bleeding, acute myocardial infarction (heart attack), • Hiatal hernia with inflammation of part of the esophagus (reflux esophagitis), • Increased heart rate (tachycardia) due to, among other things, an overactive thyroid gland (thyrotoxicosis) and insufficient pumping function of the heart (decompensated heart failure), • A certain form of muscle weakness (myasthenia gravis) and muscle weakness in the intestines (intestinal atony), especially in older or weakened patients, • Recurrent (severe) inflammation of the colon (ulcerative colitis) accompanied by fever and the secretion of mucus sometimes with the admixture of pus and blood and distension of the colon (toxic megacolon) as a complication of ulcerative colitis, • Asthma. Atropine administration should be taken into account to thicken the secretion in the bronchial tubes (bronchial secretion)., Atropine can also increase intraocular pressure by dilating the pupils and cause an attack of acute increased intraocular pressure (glaucoma).

### Are you taking any other medications?

If you are taking other medications in addition to Atropine sulfate, or have taken them recently or may use other medications in the near future, tell your doctor or pharmacist. This also applies to medications that you can obtain without a prescription.

The effect of atropine can be enhanced by simultaneous administration of drugs that counteract the action of acetylcholine, such as phenothiazines, butyrophenones, certain antiparkinsonian agents (such as amantadine), certain antidepressants (tricyclic antidepressants such as amitriptyline), and some anti-allergic agents (antihistamines such as promethazine).

The reduced intestinal motility that may be caused by atropine can affect the absorption of other drugs. For example, the absorption of levodopa (a drug for Parkinson's disease) decreases, and the absorption of digoxin (a drug for arrhythmia) in a long-acting preparation increases.

**Pregnancy and breastfeeding:** There is insufficient data on the use of this substance in pregnancy in humans to assess its possible harmful effects. There is currently no evidence of harm in animal studies. Atropine passes through the placenta and into breast milk. Use during breastfeeding is not recommended due to increased sensitivity in children.

This medication contains 3.54 mg of sodium (an important component of table salt) per ml.

Match 0.18% of the recommended maximum daily sodium intake in food for an adult.

### How to use this medicine?

Always use this medication exactly as your doctor or pharmacist has told you. Do you have doubts about the correct use? Then contact your doctor or pharmacist.

### Dosage and method of use.

**Preparation for or during surgery:** Adults: 0.25 mg - 0.6 mg atropine sulfate subcutaneously, intramuscularly or intravenously per time Maximum 1 mg per time and 2 mg per day.

**Children:** 10 - 30 µg/kg body weight subcutaneously, intramuscularly or intravenously. Maximum 400 µg per time and 1 mg per day.

As an antidote for organic phosphoric acid esters

**Adults:** 2 - 4 mg atropine sulfate intramuscularly or intravenously per time

**as initial dose**

Further administration should be based on heart rate (between 80 and 100 per minute).

**Children:** Initial dose 1 mg atropine sulfate intravenously or intramuscularly

Further administration should be based on heart rate (between 80 and 100 per minute).

As an antidote for other substances that reduce the activity of the enzyme cholinesterase (parasympathomimetics)

**Adults:** 1 - 2 mg atropine sulfate subcutaneously, intramuscularly or intravenously

**Children:** Initial dose: 0.5 mg atropine sulfate intravenously or intramuscularly.

In case of a slow heart rate due to a poorly functioning node in the heart where the impulses for contraction are produced (sinus bradycardia)

**Adults:** 0.5 mg atropine sulfate intravenously per time Maximum 2 mg per day

**Children:** 10 - 30µg/kg body weight intravenously per time Maximum 1 mg per day.

**Have you used too much of this medicine?**

Symptoms and treatment of overdose. In toxic doses, atropine causes tachycardia, rapid breathing, high fever, and stimulation of the central nervous system resulting in restlessness, confusion, excitement, and hallucinations leading to delirium. Severe intoxication causes depression of the central nervous system with hypertension or circulatory disorders and respiratory depression, coma, and death. Treatment of overdose consists of stimulation of respiration and treatment of symptoms. Artificial respiration with oxygen is necessary when breathing is impaired. Physostigmine can sometimes be effective in treating peripheral and central symptoms effects of atropine. In cases of excitement, a short-acting barbiturate can be administered to calm the patient.

**Possible side effects**

Like all medications, this medication can have side effects, although not everyone experiences them. Dry mouth or nose, thirst, reduced sweat secretion, dilation of the pupil (mydriasis), difficulty in focusing (accommodation disorders/cycloplegia), sensitivity to light (photophobia), flushing and dry skin, increased pressure within the eye (intraocular pressure), difficulty or painful urination (dysuria), acute retention of urine in the bladder due to impaired bladder emptying (acute urinary retention), constipation, rapid heartbeat (tachycardia), palpitations, and disturbances in heart rhythm (arrhythmia) have been reported. Furthermore, dizziness, headache, weakness, drowsiness, insomnia, nervousness, nausea, vomiting, loss of taste and especially mental confusion in elderly patients, perception of things that are not there (hallucinations), disorientation, and excitement. Hypersensitivity reactions, usually rash and inflamed mucous membrane of the eye (conjunctivitis), are rare.

**How to store this medication?**

- Keep out of sight and reach of children.
- Store below 25°C in the original packaging.
- Do not use this medication after the expiry date. This can be found on the box or ampoule after "Do not use after" or "EXP". It includes a month and a year. The last day of that month is the expiry date.
- Do not flush medications down the sink or toilet and do not throw them in the trash. Ask your
- pharmacist what to do with medications that you no longer use. They will be disposed of responsibly and will not end up in the environment.