

 **PACKAGE LEAFLET:**
Information for the patient

ATROPINE

Solution for injection – 1 mg / 1 ml (0.1%)
(*Atropine sulphate*)

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further question, ask your doctor or pharmacist.
- This medication 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 any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

What is in this leaflet:

1. What Atropine is and what it is used for
2. Before you take Atropine
3. How to take Atropine
4. Possible side effects
5. How to store Atropine
6. Further information

1. WHAT ATROPINE IS AND WHAT IT IS USED FOR

The active substance of this medicinal product is atropine sulphate, which has an antimuscarinic action.

Atropine temporarily blocks nerves ending, glandular secretion, relaxes certain muscles and increases the heart rate.

This drug is used:

- as premedication before anesthesia, to reduce secretion of salivary glands;
- to treat the condition characterized by weak heart beats, such as to restore the normal heart rate during cardiac arrest;
- to treat digestive tract spasms, bladder gall colics and renal colics (combined with any appropriate analgesic);
- to treat poisonings with mushrooms that contain muscarine and in organophosphorus pesticide poisoning.

2. BEFORE YOU TAKE ATROPINE

Do not take Atropine:

- if you are allergic to atropine sulphate or to any of the other ingredients of this preparation;
- if you suffer from angle-closure glaucoma;
- if you have prostatic enlargement;
- if you suffer from myasthenia gravis;
- if you suffer from paralytic ileus (in this case the colon stops its normal function);
- if you suffer from ulcerative colitis;
- if you suffer from pyloric stenosis.

Warning and precautions

Tell your doctor if:

- you have urinary retention;
- you have heart failure;
- you have had cardiac arrest;
- you suffer from chronic obstructive pulmonary disease (condition when the pulmonary air flow is reduced and you may have cough and feel like choking);

- you have a very high active thyroid;
- you have fever;
- you have diarrhea;
- you have esophageal reflux.

Taking other medicines

Tell your doctor or pharmacist if you are taking or have recently taken other medicines, including those obtained without a prescription. Inform your doctor if you are taking one of the following drugs:

- drugs for the treatment of psychoses or depression;
- amantadine (a drug for the treatment of Parkinson's disease);
- antihistamines (drugs for the treatment of allergy);
- drugs for the regulation of the heart function (disopyramide and mexiletine);
- ketoconazole (a drug for the treatment of fungal infections);
- drugs that need to be dissolved in the mouth to exert their action. This is because atropine can cause dry mouth, making the dissolution of these drugs more difficult.

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 or pharmacist for advice before taking this medicine.

Your doctor or pharmacist will discuss about the risks and benefits of taking it.

Driving and using machines

You should not engage in activities requiring complete mental alertness, such as the use of dangerous machinery and driving.

3. HOW TO TAKE ATROPINE

Atropine, solution for injection is a drug that is taken by intramuscular, subcutaneous or intravenous injection.

Injection of this drug should always be done by a doctor or nurse in charge.

Dosage: Subcutaneous or intramuscular injection: Adults, 0.5 - 1 mg, 1 up to 2 times per day. Children up to 1 year old, 0.2 mg; 1 - 6 years old, 0.2 - 0.5 mg; 6 - 15 years old, 0.3 - 0.5 mg 1 - 2 times a day. The maximal single subcutaneous dose is 1 mg, while the daily dose is 2 mg.

Intravenous injection: In this case the doses are 2 - 4 times lower compared with those injected subcutaneously or intramuscularly.

In poisoning with organophosphorus pesticides, the life of the effected patient can be saved if the intervention is realized at the right time and with sufficient doses. Usually it is injected immediately subcutaneously or intramuscularly 2 - 3 mg, and then after 2 minutes another 2 mg is injected. With these doses, pronounced sweating is reduced and signs of overdose of atropine such as mydriasis or dry mouth are noticed.

If you take more Atropine

Since dosage as well as the route of administration are determined from the doctor, and the fact that the administration will be made only by specialized medical personnel, the possibility for dosage confusion or to miss the next dose is very low.

If accidentally you have been given more medication than necessary, signs that you may have are: very fast heart rate, rapid breathing, fever, fatigue, feeling confused, and hallucinations.

You must immediately inform your doctor or nurse that administers the drug.

4. POSSIBLE SIDE EFFECTS

All medicines may cause side effects. Sometimes they are serious, most of the time they are not. Do not get alarmed by this list of possible side effects! You may not get any of them!

Tell your doctor if any of the following side effects concerns you:

- blurred vision;
- mouth dryness associated with difficulty in swallowing and talking;
- reduced bronchial secretions;
- dilatation of the pupils with loss of accommodation and inability to tolerate light; increased intraocular pressure;
- flushing;
- heat sensation;
- skin dryness;
- slow heart rate followed with rapid heart rate;
- difficulty in micturition or constipation;
- nausea, vomiting;
- confusion;
- drowsiness.

If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE ATROPINE

Keep this medicine out of the sight and reach of children! **Atropine is highly toxic!**

Do not use Atropine solution for injection after the expiry date which is stated on the pack!

Do not store above 25°C!

Keep in the original package to protect it from light and humidity!

6. FURTHER INFORMATION

What Atropine solution for injection contains

The active substance is atropine sulphate.

Each ampoule 1 ml contains 1 mg atropine sulphate.

The other excipients are: hydrochloric acid, water for injection.

Content of the pack

Box with 10 ampoules, box with 100 ampoules (for hospital use only).

Explanatory of the illustration icons on the packaging:



Ask your doctor or pharmacist.



Content.



Warning.



Solution for injection.

Marketing Authorisation Holder and Manufacturer:



PROFARMA Sh.a.
Rruga "Myslym Keta"
Tel.: 00355 4 23 89 602
Tirana - ALBANIA

This leaflet was last revised in March 2012.

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If you have to print this document please
check or uncheck the specific layers.