

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Atropine Sulphate S.A.L.F. 1 mg/ml

NEW FORMULATION

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ampoule of 1 ml contains the active ingredient Atropine Sulfate monohydrate 1 mg.

This medicine contains less than 1 mmol sodium (23 mg) per ampoule, that is to say essentially 'sodium-free'.

For the full list of the excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.

Clear and colorless solution.

4. CLINICAL INFORMATION

4.1. Therapeutic indications

Preanesthetic medication to decrease excessive salivation and secretions of the respiratory tract.

Treatment of sinus bradycardia, particularly if complicated by hypotension.

Antidote in poisoning by organophosphorus.

4.2. Posology and method of administration

Pre-anesthetic medication

Adults: The recommended dose is 0.3-0.6 mg by intravenous injection immediately before the anaesthesia induction or by intramuscular injection 30-60 minutes before the induction.

Children: The recommended dose is 0.02 mg/kg (maximum dose 0.6 mg).

Treatment of sinus bradycardia

The recommended dose is between 0.3 and 1.0 mg intravenously.

Antidote in organophosphorus poisoning

Adults: The recommended dose is 2 mg (intramuscularly or intravenously, taking into account the severity of the poisoning) every 5-10 minutes, until the skin becomes red and dry, pupils dilate and tachycardia appears.

Children: The recommended dose is 0.02 mg/kg.

4.3. Contraindications

Hypersensitivity to the active ingredient or to any of the excipients listed in section 6.1.

Angle-closure glaucoma, oesophageal reflux, pyloric stenosis, gastrointestinal obstruction, ulcerative colitis, prostatic hypertrophy, paralytic ileus, intestinal atony, myasthenia gravis (unless co-administered with anticholinesterase).

However, all these contraindications are irrelevant in potentially fatal emergency situations (such as bradyarrhythmia and poisoning).

4.4. Special warnings and precautions for use

The solution should be clear, colorless and free of visible particles.

The ampoule is intended for a single, uninterrupted administration and any unused residual solution should be discarded.

Atropine sulfate should be used with caution in children, the elderly and patients with Down syndrome. Precautions should be taken in geriatric patients for whom you may need a dose adjustment due to a possible occurrence of adverse events related to the cardiovascular system and the central nervous system.

Use with caution in patients with ileostomy or colostomy; the occurrence of diarrhoea may indicate an incomplete intestinal obstruction.

Use with caution in cases of:

- Hyperthyroidism
- Renal or hepatic insufficiency
- Coronary alterations, acute myocardial ischemia, acute myocardial infarction, tachycardia, tachyarrhythmia
- Obstructive uropathies
- Chronic obstructive pulmonary disease, because the reduction of bronchial secretions may lead to the formation of bronchial caps
- Urinary retention
- Fever or when the ambient temperature is high

Cases of atrioventricular paradoxical blockade or sinus arrest have been reported following administration of atropine in some patients after cardiac transplantation. The use of atropine for therapeutic or diagnostic procedures in patients undergoing heart transplantation should be undertaken with extreme caution.

Doses of atropine up to 1 mg slightly stimulate the central nervous system. Higher doses may induce mental disorders and central nervous system depression. Children and the elderly are particularly sensitive.

Care should be taken when using atropine in the presence of ischemia, as ischemia or infarction may be worsened.

Important information about some of the excipients:

Atropine Sulphate S.A.L.F. 1MG/ML solution for injection contains sodium.

This medicine contains less than 1 mmol sodium (23 mg) per ampoule, that is to say essentially 'sodium-free'.

4.5. Interaction with other medicinal products and other forms of interaction

Contraindicated associations

Derivatives of Belladonna: increase of the anticholinergic activity.

Halothane: attenuation of the depressor effect on heart rate.

Procainamide: increased vagal effects at atrioventricular level.

Methacholine: inhibition of the bronchoconstriction induced by methacholine inhalation.

Combinations to be taken into consideration

Other medicines with anticholinergic activity, such as tricyclic antidepressants, some anti-H1 antihistamines, antiparkinsonian medicines, disopyramide, mequitazine, phenothiazines, neuroleptic medicines, atropine antispasmodics, clozapine and quinidine, due to the risk of intensification of atropine adverse effects (urinary retention, constipation, dry mouth).

4.6. Fertility, pregnancy and lactation

Pregnancy

Data obtained from a limited number of exposed pregnancies indicate that atropine has no adverse effects on pregnancy or on the health of the fetus/newborn.

Animal studies do not indicate direct or indirect harmful effects of reproductive toxicity (see section 5.3). Studies of the pharmacokinetics of atropine in mothers and fetuses in late stage pregnancies indicate that atropine rapidly crosses the placental barrier. Intravenous administration of atropine during pregnancy or at the end of pregnancy may cause tachycardia in the fetus and in the mother. Atropine should not be used during pregnancy, unless clearly needed.

Lactation

Small amounts of atropine may pass into human breast milk. Newborns have a greater sensitivity to the anticholinergic effects of atropine. Atropine may inhibit milk production, particularly in case of repeated use. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from treatment, taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman. If you decide to continue breast-feeding during treatment, your child should be monitored for the presence of anticholinergic effects.

Fertility

No data is available on the effects of atropine sulfate on fertility in humans. Atropine sulfate has reduced the fertility of male rats, presumably as a result of the inhibitory effect on the transport of sperm and ejaculation.

4.7. Effects on ability to drive and use machines

Atropine affects your ability to drive or use machines.

4.8. Side effects

Below are the side effects of atropine organized according to the MedDRA system organ classification. There are insufficient data to determine the frequency of the single effects listed.

Endocrine disorders

Change in the levels of the growth hormone.

Metabolism and nutrition disorders

Porphyria, hyperthermia, hypothermia.

Nervous system disorders

Sedation, disorientation, dizziness, impaired short-term memory, psychosis, hallucinations (especially at higher doses), convulsions and headache.

Eye disorders

Diplopia, disturbances in accommodation, mydriasis, changes in intraocular pressure.

Cardiac disorders

Angina, arrhythmias, transient bradycardia (followed by tachycardia, palpitations and arrhythmias), atrioventricular block, hypertension, tachycardia.

Vascular disorders

Flushes.

Respiratory, thoracic and mediastinal disorders

Reduction of bronchial secretions.

Gastrointestinal disorders

Oesophageal reflux, dry mouth with difficulty swallowing and talking, nausea, vomiting, feeling of swelling, inhibition of gastric secretion.

Skin subcutaneous tissue

Redness and dryness of the skin, hives, rash. In case of intramuscular administration, a reduced activity of the sweat glands can be observed.

Renal and urinary disorders

Inhibition of the parasympathetic control of the urinary bladder, urinary retention.

General disorders and administration site conditions

Hypersensitivity reactions - Anaphylactic reactions.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form: <https://sideeffects.health.gov.il>.

4.9. Overdose

Symptoms:

In case of an overdose of the medicine, you may have the intensification of the side effects described. In particular, dryness of mucous membranes, dilated pupils, tachycardia, fever and skin rash are possible; neurological symptoms such as confusion, hallucinations, etc., that can persist for 48 hours or more, can also be observed. In some cases, respiratory depression, coma, circulatory collapse and death can be observed.

Treatment:

At the first signals, in the case of respiratory depression, it is recommended to administer oxygen and, in the case of a persistence of seizures, if the circulatory conditions allow it, proceed with an intravenous administration of short-acting barbiturates (e.g. thiopental) or benzodiazepines (e.g. diazepam). Since atropine is excreted through the kidneys, an intravenous administration of fluids is recommended. In case of delirium and coma, the administration of physostigmine by a slow intravenous infusion at a dose range of 1 to 4 mg (0.5 to 1 mg in children) is recommended.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: Belladonna alkaloids, tertiary amines.

ATC code: A03BA01

Atropine is an antimuscarinic alkaloid. It acts as an antagonist of peripheral muscarinic cholinergic receptors, which become insensitive to the action of acetylcholine that is released by the parasympathetic autonomic endings. This elective action explains the pharmacotherapeutic activity of the product.

5.2. Pharmacokinetic properties

Distribution

Atropine is rapidly distributed in the tissues after an intravenous administration (distribution volume of 3.297 l/kg in normal subjects).

Atropine crosses the blood-brain barrier and has a half-life of 4 hours.

Metabolism and excretion

About half of a dose is metabolized and eliminated in the liver, while the remaining half is excreted unaltered in the urine. Atropine crosses the placenta and traces appear in breast milk.

5.3. Preclinical safety data

In preclinical studies, effects were observed only at exposures considered sufficiently in excess of the maximum human exposure, which indicates little clinical relevance. Atropine sulfate has reduced fertility in male rats, presumably as a result of an inhibitory effect on the transport of sperm and ejaculation.

6. PHARMACEUTICAL INFORMATION

6.1. List of the excipients

Each ampoule contains:

Sodium chloride, Hydrochloric acid, Water for injections.

6.2. Incompatibilities

The medicine must not be mixed with alkali.

6.3. Shelf life

The expiry date of the product is indicated on the packaging materials.

The product should be used immediately after opening.

Any unused residual solution should be discarded.

6.4. Special precautions for storage

Store in the original package to protect the medicine from light.

Store below 25°C.

6.5. Nature and capacity of the container

Yellow, Type I glass ampoule.

Each package contains 5 ampoules of 1 ml.

6.6. Special precautions for disposal and other handling

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

7. MARKETING AUTHORIZATION HOLDER and IMPORTER

RAZ PHARMACEUTICS LTD., 31 Gesher Haetz street, Industrial Park, Emek Hefer, Israel

8. MARKETING AUTHORIZATION NUMBER

159-21-34594-00.

Revised in October 2025.

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