

# **ATROPINE TEVA 20 mg/10 ml**

## **Solution for I.V. or I.M. Injection**

### **1. NAME OF THE MEDICINAL PRODUCT**

Atropine Teva 20 mg/10 ml

### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each ampule of 10 ml of solution contains:

Active ingredient:

Atropine sulfate 20 mg.

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

### **3. PHARMACEUTICAL FORM**

Solution for injection.

Clear, colorless solution.

### **4. CLINICAL PARTICULARS**

#### **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**

##### **Preanesthetic medication**

*Adults:* The recommended dose is 0.3-0.6 mg by intravenous injection immediately before the anesthesia 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 poisoning by organophosphorus

*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, the 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. Angle-closure glaucoma, esophageal reflux, pyloric stenosis, gastrointestinal obstruction, ulcerative colitis, prostatic hypertrophy, paralytic ileus, intestinal atony.

#### **4.4 Special warnings and precautions for administration**

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

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

Precautions must be taken in geriatric patients for whom you may need a dose adjustment for 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 diarrhea may indicate an incomplete intestinal obstruction. Use with caution in cases of myasthenia gravis, hyperthyroidism, coronary artery disease, acute myocardial ischemia, tachycardia, tachyarrhythmia, prostatic hypertrophy and other obstructive uropathies.

Important information about some of the excipients:

This medicinal product contains about 34.5 mg sodium per ampoule.

#### **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 the heart rate.

*Procainamide:* increased vagal effects at atrioventricular level.

*Methacholine:* inhibition of the bronchoconstriction induced by methacholine inhalation.

#### **4.6 Pregnancy and lactation**

Animal studies are insufficient to determine possible effects related to the use of the drug during pregnancy or lactation. The potential risk for humans is not known.

Use with caution and only when necessary.

#### **4.7 Effects on ability to drive and use machines**

Atropine has a considerable influence on the ability to drive or use machines.

#### **4.8 Undesirable 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.

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.

Respiratory, thoracic and mediastinal disorders

Reduction of bronchial secretions.

Gastrointestinal disorders

Esophageal regurgitation.

Skin subcutaneous tissue

Redness and dryness of the skin. In the case of intramuscular administration, a reduction in the activity of the sweat glands can be observed.

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

<http://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>

## 4.9 Overdose

### Symptoms

In case of an overdose of the drug, 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 signs, 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 permit 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 cases 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 by the liver, while the remaining half is excreted unchanged in the urine. Atropine crosses the placenta and traces appear in breast milk.

### 5.3 Preclinical safety data

Preclinical data reveal no special hazard for humans based on conventional studies of safety pharmacology and reproductive toxicity.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of the excipients

Sodium chloride, sulphuric acid 96% (q.s. for pH adjustment), sodium hydroxide (q.s. for pH

adjustment), water for injections q.s. to 10 ml.

### **6.2 Incompatibility**

The medicinal product 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 below 25°C.

### **6.5 Nature and contents of container**

Amber glass ampoule.

Each package contains 5 ampoules of 10 ml.

### **6.6 Special precautions for disposal**

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

## **7. MANUFACTURER AND LICENCE HOLDER**

Teva Pharmaceutical Industries Ltd.,  
P.O.Box 3190, Petah-Tikva

## **8. MARKETING AUTHORIZATION NUMBER**

021.02.27809

This leaflet, in the format determined by the Ministry of Health, was updated on May 2019 and the content is in accordance with the reference leaflet that was checked and approved by the Ministry of Health in August 2017 and updated in July 2018.