



MercuryPharma

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT  
**Atropine Sulphate 600 micrograms/ml  
Solution for Injection**

**Read all of this leaflet carefully before you are given this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, nurse or pharmacist.
- This medicine 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 you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

The name of your medicine is Atropine Sulphate 600 micrograms/ml Solution for Injection. It will be referred to as Atropine Sulphate Injection for ease hereafter.

**What is in this leaflet:**

1. What Atropine Sulphate Injection is and what it is used for
2. What you need to know before you are given Atropine Sulphate Injection
3. How you are given Atropine Sulphate Injection
4. Possible side effects
5. How to store Atropine Sulphate Injection
6. Contents of the pack and other information

**1. WHAT ATROPINE SULPHATE INJECTION IS AND WHAT IT IS USED FOR**

Atropine Sulphate Injection contains the active substance Atropine Sulphate which belongs to a group of medicines called cholinesterase inhibitors. It has the effect of reversing the action of certain muscle-relaxing drugs. The effects of atropine include an increase in heart rate, a decrease in production of saliva, sweat, bronchial and intestinal secretions, and a decrease in the movements of the intestine.

Atropine Sulphate Injection is used in the following conditions:

- during anaesthesia to dry up secretions in the mouth and chest and to keep heart beat normal
- in the treatment of poisoning caused by certain substances like pesticides
- to reverse the effects of certain drugs given during surgery to relax muscles
- to prevent slowing of the heartbeat during CPR (emergency procedure undertaken to revive the heart when it has suddenly stopped)
- to reverse over activity of certain substances (cholinergic crises) in myasthenia gravis (a condition where muscles become easily fatigued and weak due to defect in nerve-muscle stimulation).

**2. WHAT YOU NEED TO KNOW BEFORE YOU ARE GIVEN ATROPINE SULPHATE INJECTION**

**You should not be given Atropine Sulphate Injection**

- if you are allergic to Atropine Sulphate or any of the other ingredients of this medicine (listed in section 6)
- if you have muscle weakness (myasthenia gravis)
- if you suffer from a disease of the colon and rectum (severe ulcerative colitis)
- if you suffer from glaucoma (increased pressure in the eye)
- if you suffer from paralytic ileus (a condition of the gut that causes severe constipation and bloating caused by inactivity of your intestines)
- if you suffer from pyloric stenosis (a narrowing of the opening from the stomach to the intestine)
- if you suffer from toxic megacolon (dilated colon accompanied by bloating, fever and abdominal pain)
- if you have an overactive thyroid gland
- if you suffer from reflux oesophagitis (a condition that causes severe heart burn)
- if you suffer from enlargement of the prostate.

Make sure your doctor knows if you suffer from any of these.

**Warnings and precautions**

Talk to your doctor, nurse or pharmacist before you are given Atropine Sulphate Injection:

- if you are elderly (65 years of age or older)
- if the person receiving this medicine is a child
- if you have problems associated with mental and physical growth (Down's syndrome)
- if you have loose watery stool
- if you have had a heart transplantation
- if you have chronic pulmonary disease where the airflow to your lungs is restricted and you may cough and feel breathless
- if you have heartburn or indigestion
- if you have an abnormally fast heart beat due to an overactive thyroid gland or due to heart surgery
- if you have kidney or liver disease
- if you suffer from high blood pressure
- if you have a rapid, irregular heartbeat
- if you have damage to the nerves
- if you have a stomach ulcer or infection of the stomach or intestines
- if you have a hiatus hernia (protrusion of the upper part of the stomach into the chest)
- if you have a fever
- if you are suffering from angina (a type of chest pain), heart failure, heart disease or are having a heart attack
- if you are pregnant or breast feeding.

Tell your doctor if any of these apply to you.

**Children**

- atropine sulphate injection should be used with caution in children having fever with a high body temperature or if the air temperature around you is hot
- high doses of Atropine Sulphate Injection should be used with caution in children and older patients as it may cause mental problems and depression of the central nervous system (characterized by decreased rate of breathing, decreased heart rate or loss of consciousness).

**Other medicines and Atropine Sulphate Injection**

Tell your doctor, nurse or pharmacist if you are taking, have recently taken or might take any other medicines. This includes any herbal products or medicines bought without a prescription.

- disopyramide, mexilitine, quinidine (for irregular heart beats)
- clozapine, olanzepine (for treatment of mental disorders)
- domperidone, metoclopramide (for vomiting)
- ketoconazole (for fungal infection)
- medicines that you take by allowing them to dissolve slowly in your mouth - atropine may cause your mouth to become dry, making it more difficult for these medicines to dissolve (e.g. nitrates used to treat chest pain)
- antihistamines (for allergy)
- phenothiazine or butyrophenone drugs (for anxiety or for more serious mental illness, or to relieve feeling or being sick)
- tricyclic antidepressants, Monoamine Oxidase Inhibitors (to relieve depression)
- amantadine used to treat Parkinsonism (a disorder in the brain causing muscle stiffness and shaking)
- dicyclomine (antispasmodic drug)

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*continued overleaf*

Package leaflet: Information for the patient

**Atropine Sulphate  
600 micrograms/ml  
Solution for Injection**



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AMS Component No.: **LF-118123-01**  
**Proof Number:** 1  
Revision Date: 24-May-2019  
Product Description: Atropine SO4 600 mcg/ml Inj UK 10 Amp  
Component: Leaflet  
Product Code: 100405  
Country: UK  
Vendor Name: B Braun Medical UK Limited  
CRF(s): PR 31367  
Revised by: VDD

Dimension: 155 x 447 mm  
Commodity No.: N/A  
Pharma Code: N/A  
Core Spec Ref.: N/A  
Print Colours: Black  
Non-Print Colours: **Cutter**  
Min. Font Size: 8.5 pt

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- beta blockers (e.g propranolol) used to treat hypertension
- chlorpromazine used to treat schizophrenia
- neostigmine used to treat symptoms of myasthenia gravis.

#### **Pregnancy, breast-feeding and fertility**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

#### **Pregnancy**

Atropine Sulphate Injection should only be used during pregnancy when your doctor decides the benefits to you are greater than any possible risk to the unborn baby.

#### **Breast-feeding**

Atropine Sulphate Injection should only be used during breast-feeding when your doctor decides the benefits to you are greater than any possible risk to the breast-feeding infant.

**Ask your doctor or pharmacist for advice before taking any medicine.**

#### **Driving and using machines**

Atropine Sulphate injection may cause drowsiness, blurred vision, confusion and hallucinations and patients should be advised not to drive or operate machinery if affected.

### **3. HOW YOU ARE GIVEN ATROPINE SULPHATE INJECTION**

Atropine Sulphate Injection is administered by injection into a vein, into the muscle or into the tissue just beneath the skin.

Your doctor will decide the correct dose for you, depending on your circumstances. Your dose may be calculated according to your age, body weight, severity of the symptoms and previous responses to similar medicines.

#### **If you are given more Atropine Sulphate Injection than you should**

This is unlikely because the dose will be administered by a healthcare professional. An overdose may cause difficulty in breathing, restlessness, hallucinations (seeing things that are not there) and occasionally convulsions. If you suspect you have been given too much, you should tell the doctor immediately.

If you have any further questions on the use of this product ask your doctor.

### **4. POSSIBLE SIDE EFFECTS**

Like all medicines, this medicine can cause side effects, although not everybody gets them. Some side effects can be serious and you should tell your doctor immediately if you notice the following:

- any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body) should be reported to a doctor immediately.

The following side effects have also been reported:

#### **Very rare (may affect up to 1 in 10,000 people)**

- heart conduction problems (slowed AV-conduction or increase of existing AV-block).

#### **Not known: frequency cannot be estimated from the available data**

- confusion (especially in elderly)
- sensing things that do not exist (hallucinations)
- dizziness
- restlessness
- delirium
- blurred vision
- dilation of pupils (Mydriasis)
- inability to tolerate light
- an increase in pressure within the eyes
- slow heart beat followed by fast heart beat
- rapid heart beat (palpitation)
- irregular heart beat
- worsening of heart attack (characterized by chest pain, sweating, anxiety, difficulty in breathing)
- flushing
- drowsiness
- inhibition of gastric secretion
- pain behind the breast bone (retrosternal pain).
- dry mouth with difficulty in swallowing
- thirst
- dryness of the skin
- difficulty in passing urine or
- constipation
- vomiting (being sick), nausea (feeling sick)
- rashes, peeling of the skin, hives
- fever
- reduced phlegm (this can make phlegm more difficult to cough up)
- increase in body temperature.

#### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

### **5. HOW TO STORE ATROPINE SULPHATE INJECTION**

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label, carton. The expiry date refers to the last day of that month.

Do not store above 25°C.

Keep in original container in order to protect from light.

If only part used, discard the remaining solution.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

### **6. CONTENTS OF THE PACK AND OTHER INFORMATION**

#### **What Atropine Sulphate Injection contains**

The active substance is Atropine Sulphate. Each ampoule contains 600 micrograms of Atropine Sulphate in 1ml of solution.

The other ingredients of the each ampoule are dilute sulphuric acid and water for injections.

#### **What Atropine Sulphate Injection looks like and contents of the pack**

Atropine Sulphate Injection is a clear, colourless sterile solution for injection.

Each glass ampoule (a small bottle) contains 1ml of solution which contains 600 micrograms of Atropine Sulphate.

Each carton contains ten 1ml ampoules of Atropine Sulphate Injection.

#### **Marketing Authorisation Holder**

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#### **Manufacturer**

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