

## **Package leaflet: Information for the patient**

### **Atropine Sulfate 600 micrograms/ml Solution for Injection** atropine sulfate

**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 Sulfate 600 micrograms/ml Solution for Injection; it will be called Atropine Sulfate Injection for ease here after.

#### **What is in this leaflet:**

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

#### **1. What Atropine Sulfate Injection is and what it is used for**

Atropine Sulfate Injection contains the active substance Atropine

Sulfate, which belongs to a group of medicines called anticholinergic drugs. 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 Sulfate Injection is used in the following conditions:

- during anaesthesia to reduce the risk of slowing of the heart and dry up secretions in the mouth and chest
- in the treatment of poisoning caused by certain substances like pesticides
- to reverse the effects of certain drugs given to relax muscles
- to prevent slowing of the heartbeat during the use of emergency procedure undertaken to revive the heart when it has suddenly stopped or you have stopped breathing
- to reverse over activity of certain substances used in treatment of a condition where muscles become easily fatigued and weak due to defect in nerve-muscle stimulation (myasthenia gravis). These substances may cause symptoms such as breathing problems and sweating.

## **2. What you need to know before you are given Atropine Sulfate Injection**

### **You must not be given Atropine Sulfate Injection**

- if you are allergic to Atropine Sulfate or any of the other ingredients of this medicine (listed in section 6)
- if you have muscle weakness (myasthenia gravis)
- if you suffer from toxic megacolon (dilated colon accompanied by bloating, fever and abdominal pain)
- if you suffer from reflux oesophagitis (a condition that causes severe heart burn)
- if you suffer from a condition which narrows the opening from the stomach (pyloric stenosis) to the intestine leading to intestinal blockage
- 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 increased pressure in the eye (glaucoma)
- if you suffer from enlargement of the prostate gland.

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 Sulfate 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 an overactive thyroid gland
- 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 sulfate 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 Sulfate 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 Sulfate Injection**

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

In particular, tell your doctor if you are taking any of the following:

- antihistamines (for allergy)
- phenothiazine or butyrophenones (for anxiety or for more serious mental illness, or to relieve feeling or being sick)
- tricyclic antidepressants (to relieve depression)
- amantadine used to treat a disorder in the brain causing muscle stiffness and shaking (Parkinsonism), or viral infections
- anticholinesterase drugs (used for a condition where muscles become easily fatigued and weak due to defect in nerve-muscle stimulation). If you are taking anticholinesterase drugs such as neostigmine or pyridostigmine, they should be withdrawn, if necessary for several days, before you are given Atropine Sulfate Injection
- butyrophenones used to treat schizophrenia (e.g. haloperidol, triperidol) and as an antiemetic (e.g. domperidone)
- you are to receive ether (a general anaesthetic).

If you are already taking one of these medicines, speak to your doctor before you are given Atropine Sulfate Injection.

**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 for advice before taking this medicine.

**Pregnancy**

Atropine Sulfate 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 Sulfate 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.

**Driving and using machines**

This is unlikely to be applicable as you will not feel well enough to drive or use machinery. Consult your doctor before considering such action.

### **3. How you are given Atropine Sulfate Injection**

Atropine Sulfate 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 Sulfate Injection than you should:**

This is unlikely because this medicine will be administered by a doctor. If you are concerned about the dose, discuss this with your doctor.

An overdose may cause difficulty in breathing, restlessness, seeing things that are not there (hallucinations), severe confusion or excitement (delirium) and occasionally convulsions, dry mouth or burning sensation in mouth, difficulty in swallowing, nausea, vomiting, rash, dryness of the skin, redness in the face and other areas of the skin, sleepy mode or drowsiness, avoidance or intolerance of light, increased body temperature, high blood pressure, irregular heart rate. In severe cases, the breathing rate and heart rate may slow significantly, which may lead to coma. 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:

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

- heart conduction problems (slowed AV-conduction or increase of existing AV-block)
- headache
- confusion
- sensing things that do not exist (hallucinations)
- dizziness
- restlessness
- delirium
- blurred vision
- dilation of pupils (Mydriasis)
- difficulty in adjusting the vision for various distances
- 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
- pain behind the breast bone (retrosternal pain).
- dry mouth with difficulty in swallowing
- thirst
- increase in the severity of heart attack
- dryness of the skin
- difficulty in passing urine or constipation
- vomiting (being sick), nausea (feeling sick)
- rashes, peeling of the skin
- fever
- inhibition of gastric secretion
- loss of taste
- swelling in the abdomen
- 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 HPRA

Pharmacovigilance Website: [www.hpra.ie](http://www.hpra.ie).

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

### **5. How to store Atropine Sulfate 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 carton and ampoule label after 'Exp'. The expiry date refers to the last day of that month.

Do not store above 25°C. Keep ampoules in the outer carton in order to protect from light.

For single use only. Once the ampoule has been opened it should be used immediately.

If only part used, discard the remaining solution.

Do not use if the ampoule is damaged or if the contents are discoloured or deteriorated. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

### **6. Contents of the pack and other information**

#### **What Atropine Sulfate Injection contains**

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

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

**What Atropine Sulfate Injection looks like and contents of the pack**

Atropine Sulfate Injection is a clear, colourless sterile, aqueous solution for injection in 1ml clear glass ampoule.

Pack size: 10 ampoules are packaged together in carton.

**Marketing Authorisation Holder**

Mercury Pharmaceuticals (Ireland) Ltd, 4045, Kingswood Road, City West Business Park, Co Dublin, Ireland.

**Manufacturer**

B. Braun Melsungen AG, Mistelweg 2, 12357 Berlin, Germany.

**This leaflet was last revised in March 2021.**