



## **Atropine Sulfate Injection USP 0.6mg/1ml, 0.4mg/1ml, 8mg/20ml**

### **Package Leaflet: Information for the user**

Atropine Sulphate

**Read all of this leaflet carefully before you start using 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, please ask your doctor, pharmacist or nurse
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

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

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

### **1. What Atropine Solution for injection is and what it is used for**

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Atropine Solution for injection belongs to a group of medicines known as anticholinergics. These medicines are often used:

- before general anaesthesia to reduce saliva secretions
- to restore normal heartbeat during a cardiac arrest
- as an antidote to some insecticides and in mushroom poisoning.
- In combination with other drugs to reverse the effect of muscle relaxants used during surgery.

### **2. What you need to know before you are given Atropine Solution for injection**

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#### **You should not be given Atropine Solution for injection if:**

- you are allergic to Atropine Sulfate or to any of the other ingredients of this medicine (listed in section 6).
- you suffer from closed-angle glaucoma (a condition that affects your eyes).
- you are a man with an enlarged prostate.
- you suffer from myasthenia gravis (weakness of breathing muscles).
- you suffer from pyloric stenosis (narrowing of the opening that takes away food from your stomach).
- you suffer from paralytic ileus (your intestine stops functioning properly)
- you suffer from ulcerative colitis – a disease of the colon and rectum.

### **Warnings and precautions**

Talk to your doctor, pharmacist or nurse before being given Atropine Solution for injection if:

- you have urinary difficulties
- you have heart failure
- you have had heart attack
- you have a heart transplant
- you have chronic obstructive pulmonary disease (a condition where the airflow to your lungs is restricted and you may cough and feel breathless)
- you have an overactive thyroid
- you have high blood pressure
- you have a fever
- you are suffering from diarrhoea
- you have reflux oesophagitis (heartburn)

**Other medicines and Atropine Solution for injection:**

Tell your doctor, pharmacist or nurse if you are taking, have recently taken, or might take any other medicines including medicines obtained without prescription.

**Other medicines which may interact with Atropine Solution for injection are:**

- medicines to treat psychosis or depression.
- amantidine (a medicine for Parkinson's disease)
- antihistamines (medicines to treat hayfever and allergies)
- medicines to regulate your heart (disopyramide and mexiletine)
- ketoconazole (a medicine to treat fungal infections)

- 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.

**Pregnancy, fertility and breast-feeding**

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

**Driving and using machines**

You should not drive or use machinery if affected by the administration of Atropine Solution for injection.

**3. How Atropine Solution for injection is given**

Your nurse or doctor will give you the injection.

Your doctor will decide the correct dosage for you and how and when the injection will be given.

**If you think you have been given too much Atropine Solution for injection:**

Since the injection will be given to you by a doctor or nurse, it is unlikely that you will be given too much. If you think you have been given too much or you begin to feel your heart beating very fast, you are breathing quickly, have high temperature, feel restless, confused, have hallucinations, or lose co-ordination you must tell the person giving you the injection immediately.

**4. Possible side effects**



Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects have been reported.

**Contact your doctor or nurse immediately if you get any of the following:**

- Sudden life – threatening allergic reaction such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing.

Other Side effects include:

- drowsiness
- blurred vision
- dry mouth with difficulty swallowing
- thirst
- dilation of the pupils
- flushing
- dryness of the skin
- slow heart beat followed by fast heart beat
- palpitations (you are aware of your heart beating)
- difficulty in passing urine or constipation
- vomiting
- confusion especially in the elderly or severe confusion
- coughing and bringing up phlegm ( bronchial plugs)
- restlessness
- hallucinations
- changes in the way the heart beats (arrhythmias)

- heart condition ( atrioventricular block) after heart transplantation
- fever

### **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.

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

### **5. How to store Atropine Solution for injection**

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Keep out of the sight and reach of children.

You should not be given this medicine if it has passed the expiry date shown on the ampoule label. The expiry date refers to the last day of that month. The doctor or nurse will check that the product has not passed this date.

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

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#### **What Atropine Solution for injection contains:**

The active ingredient is Atropine Sulfate 0.1% w/v. The other ingredients are sodium chloride and water for injections. It may also include sodium hydroxide and sulfuric acid to make a neutral solution.

#### **What Atropine Solution for injection looks like and contents of the pack:**



Atropine Solution for injection is a clear, colourless solution supplied in glass ampoules each containing 1ml. The ampoules are supplied to your pharmacist or doctor in packs of 10.

**7.Manufactured in India by:**

**TAJ PHARMACEUTICALS LTD.**

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