Package leaflet: Information for the user

Atropine Sulfate 3mg in 10ml Solution for injection in pre-filled syringe

Read all of this leaflet carefully before you are given Atropine Solution for injection because it contains important information for you.

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

Atropine belongs to a group of medicines called antimuscarinics. These medicines are often used in anaesthesia to reduce the flow of saliva and other body fluids. Atropine may also act on the vagus nerve (a nerve that sends information from the brain to other parts of the body). This helps to make the heart beat faster.

Atropine Injection is used to raise the heart rate if it has become too slow after a heart attack or to restart the heart.

Atropine Injection is also used to treat pesticide and mushroom poisoning and can be used as an antidote for overdose of cholinesterase inhibitors (a type of medicine usually used to treat the symptoms of Alzheimer's disease).

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

You should not be given Atropine Solution for injection if you:

- are allergic to atropine sulfate or any of the other ingredients of this medicine (listed in Section 6).
- have urination difficulties.
- have elevated pressure in the eye (glaucoma).
- have a disease of the muscles causing drooping eyelids, double vision, difficulty in speaking and swallowing and sometimes muscle weakness in the arms or legs (myasthenia gravis).
- are breast-feeding.
- have a condition called pyloric stenosis which means that it is difficult for food to move from your stomach into the small intestine (and which causes pain or vomiting).
- have an inflamed gut with symptoms of blood and mucus in the faeces.

Talk to your doctor, pharmacist or nurse if you:

- suffer from an overactive thyroid or other thyroid problems.
- suffer from prostatic disease.
- suffer from liver or kidney disease.
- have had a heart attack or heart failure.
- have an irregular heart rhythm.
- have fever or when the room temperature is high.
- are elderly.
- have lung disease.

3. How Atropine Solution for injection is given

Your doctor will decide the correct dose you require. It will be given into a muscle or a vein (if a suitable vein is not available then it could be administered using an endotracheal ET tube which is inserted into the windpipe).

Your doctor will decide the correct dose you require for adults, the elderly and children over 12 years of age:

- As treatment to restart the heart:
  - 3mg (in 10ml) into a vein
  - repeated if necessary up to a maximum dose of 6mg.

- As an antidote to cholinesterase inhibitors:
  - 2mg into a vein or muscle
  - repeated every 5-10 minutes until symptoms are reversed.

4. Possible side effects

Like all medicines Atropine Solution for injection can cause side effects, although not everybody gets them.

The following side effects have been reported:

- Hallucinations
- Confusion especially in the elderly
- Sudden life-threatening allergic reaction such as rash, itching or swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing.

Other side effects include:

- Blurred vision
- Increase in pressure in the eye
- Dry mouth
- Nausea
- Thirst
- Diminished or blurred vision
- Uncomfortable sensitivity to light (photophobia)
- Decrease in tear production in the eyes
- Flushing
- Dizziness of the skin
- Fast heart beat (tachycardia)
- Palpitations (you are aware of your heart beating)
- Difficulty in passing urine
- Constipation
- Vomiting
- Nervousness
- Confusion especially in the elderly
- Thickening of the phlegm produced while coughing
- Restlessness
- Hallucinations
- Changes in the way the heart beats (arrhythmias)
- Severe confusion (delirium)

Reporting of side effects

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme. Website: www.mhra.gov.uk/yellowcard.

5. How to store Atropine Solution for injection

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 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.

Store below 25°C. Protect from light.

6. Contents of the pack and other information

What Atropine Solution for injection contains:

- Each ml of solution contains 0.3 mg of the active substance Atropine Sulfate.
- Each pre-filled syringe (10 ml) contains 3 mg of the active substance Atropine Sulfate.
- The other ingredients are water for injections, sulfuric acid and sodium nitrate.

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

Atropine Injection is a clear, colourless solution supplied in 10ml prefilled syringes.

There are no needles provided with this pre-filled syringes.

The Marketing Authorisation Holder:

Aurum Pharmaceuticals, T/A Martinvale Pharma, Bampton Road, Harold Hill, Romford, RM3 8UG, United Kingdom.

Manufacturer:

Aurum Pharmaceuticals, T/A Martinvale Pharma, Bampton Road, Harold Hill, Romford, RM3 8UG, United Kingdom.

Product Licence Number: PL 12064/0057

This leaflet was last revised in: December 2016