

ATROPINE INJECTION BP MINIJET® 100 micrograms/ml

SOLUTION FOR INJECTION

Atropine Sulfate

Patient Information Leaflet

Read all of this leaflet carefully

Please note this medicine is mainly used in emergency situations in which case the doctor will have decided that you needed it.

It is unlikely, therefore, that you will have read this leaflet before the medicine was administered to you.

- Keep this leaflet. You may need to read it again
- If you have any further questions, ask the doctor or nurse
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell the doctor or nurse.

In this leaflet:

1. What Atropine Injection BP Minijet is and what it is used for
2. Before or after you are given Atropine Injection BP Minijet
3. How to use Atropine Injection BP Minijet
4. Possible side effects
5. How to store Atropine Injection BP Minijet
6. Further information.

1. What Atropine Injection BP Minijet is and what it is used for

Your medicine is called Atropine Injection BP Minijet.

Atropine is an antimuscarinic. It temporarily blocks some nerve endings. This stops glands secreting, makes some muscles (such as in the gut) relax and speeds up the heart.

This medicine is used for:

- Pre-medication before an anaesthetic to dry the mouth and throat before surgery
- During anaesthetic it is used to prevent a slow heart rate and restore blood pressure.
- To treat a very slow heart beat
- To treat a heart attack
- To treat poisoning from insecticides, nerve gas or poisonous mushrooms
- To control the side effects of neostigmine (a medicine which increases nerve impulses to the muscles).
- As part of an emergency procedure to manually maintain brain function after a heart attack. It is used to treat a slow heart beat occurring with low blood pressure, decreased blood flow or an irregular heart rate.

2. Before or after you are given Atropine Injection BP Minijet

You should not be given Atropine if you suffer from any of the following:

- Reflux oesophagitis (a condition that causes severe

heart burn, increased belching and upper stomach pain)

- Closed angle glaucoma (an eye condition that causes sudden blurred vision with pain and redness)
- Myasthenia gravis (a condition that causes extreme tiredness and muscle weakness)
- Paralytic ileus (a condition of the gut that causes severe constipation and bloating caused by inactivity of your intestines)
- Severe ulcerative colitis, or have a blockage in your intestines
- Allergy to the active ingredient, atropine sulfate, or to any of the ingredients in the medicine (see section 6)
- Trouble passing water (e.g. due to an enlarged prostate gland).

Take special care

Tell your doctor if you have/are any of the following:

- Pregnant or breast-feeding
- High blood pressure
- Liver, kidney or lung disease
- Hyperthyroidism (where your body makes too much thyroid hormone)
- Nervous system problems
- Raised temperature
- Stomach ulcer
- Hiatus hernia (this occurs in the upper part of the stomach)
- Diarrhoea, gastroenteritis or any other infection of the gut.
- Heart problems
- Acid reflux (heart burn)
- Elderly or a child

Using other medicines

Tell the doctor if you are taking any of the following:

- Prescribed medicines, especially:
 - o Tricyclic antidepressants
 - o Drugs for Parkinson's disease
 - o Some antihistamines
 - o Antispasmodics (e.g. for irritable bowel syndrome)
 - o Phenothiazines (for mental illness)
 - o Disopyramide or quinidine (for heart problems).
 - o Propofol (an anesthetic)
 - o Dobutamine and other catecholamines (for heart failure)
- Any medicines available without prescription.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before using any medicine.

Atropine is excreted in breast milk. If atropine is given to pregnant women it may cause the foetus to have a fast heart rate. Atropine will only be given to

pregnant or breast-feeding women if the benefit outweighs the risk.

3. How to use Atropine Injection BP Minijet

This medicine will be given to you as an injection by the doctor.

This injection will be given either:

- Into a vein
- Into a muscle
- Under the skin
- Via a breathing tube in your windpipe.

The doctor will decide what dose is right for you and this will depend on what it is being used to treat.

If you are given more Atropine than you should

The signs of overdose include a dry mouth with a burning sensation, difficulty swallowing, being sick, fast heart rate, restlessness and confusion followed by increasing drowsiness and reduced function of your heart and lungs. If you think you have been given too much Atropine talk to your doctor.

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

4. Possible side effects

As with all medicines, Atropine Injection BP Minijet may cause some side effects although not everybody gets them.

Seek immediate medical help if you have an allergic reaction. This includes any of the following symptoms:

- Difficulties in breathing
- Swelling of your eyelids, face or lips
- Rash or itching especially those covering your whole body
- Collapse.

Other side effects are:

- Heart attack
- A faster or irregular heartbeat
- Reduced saliva (spit), sweat and phlegm (this can make phlegm more difficult to cough up)
- Hallucinations, confusion and/or excitement (especially in the elderly)
- Increased eye pressure or enlarged pupils (this may make your vision blurred)
- Constipation or difficulty in passing urine
- A skin rash with red, raised itchy bumps. The skin rash may get worse and form scales or flakes of skin that fall off
- Headache
- A feeling of nervousness, drowsiness or dizziness
- Sleeplessness
- Loss of taste
- Weakness
- Bloated feeling
- Feeling sick or being sick
- Blushing.

Side effects are more likely with higher doses, but usually disappear once treatment stops.

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:

Ireland

HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2;

Tel: +353 1 6764971; Fax: +353 1 6762517.

Website: www.hpra.ie;

E-mail: medsafety@hpra.ie.

United Kingdom

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard

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

5. How to store Atropine Injection BP Minijet

This medicine will be stored for you by the doctor under the following conditions:

- Keep out of the reach and sight of children
- Do not store above 25°C
- Keep the vial in the outer carton.

Do not use this medicine after the date shown on the carton and vial label. The expiry date refers to the last day of the month.

Once opened: Use immediately. Discard any unused portion.

Do not dispose of this medicine via waste water or household waste. This will help to protect the environment.

6. Further Information

This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask the doctor or nurse who will have the information you need and will advise you.

What Atropine Injection BP Minijet contains

The active substance is a tropine sulfate, 100micrograms/ml available in a 5ml, 10ml or 30ml vial.

To make it into an injection, it also contains: sodium citrate dihydrate, citric acid monohydrate, sodium chloride and water for injections.

This medicinal product contains less than 1mmol sodium (23mg) per dose ,i.e. essentially sodium free.

What Atropine Injection BP Minijet looks like and contents of the pack

Solution for injection. The container consists of a 5ml, 10ml or 30ml pre- filled glass vial with an injector device.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

DLRC Pharma Services Limited, Chesterfield House, Clonmannon, ASHFORD, County Wicklow, A67WR29, Ireland

Manufacturer:

UCB Parma Ltd., 208 Bath Road, Slough, Berkshire, SL1 3WE, UK

Date of preparation of the leaflet: January 2019