

Atracurium besilate 10 mg/ml solution for injection

Important information about your medicine

- ▶ Your doctor or nurse will give you the injection.
- ▶ If this injection causes you any problems talk to your doctor, nurse or pharmacist.
- ▶ Please tell your doctor or pharmacist, if you have any other medical conditions or have an allergy to any of the ingredients of this medicine.
- ▶ Please tell your doctor or pharmacist, if you are taking any other medicines.

Read all of this leaflet carefully before you start using this medicine.

- *Keep this leaflet. You may need to read it again.*
- *If you have any further questions, ask your doctor or pharmacist.*
- *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 become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.*

The name of your medicine is Atracurium 10 mg/ml solution for injection, which will be referred to as Atracurium throughout this leaflet.

In this leaflet:

1. What Atracurium is and what it is used for
2. Before you receive Atracurium
3. How to use Atracurium
4. Possible side effects
5. How to store Atracurium
6. Further information

1. WHAT ATRACURIUM IS AND WHAT IT IS USED FOR

Atracurium belongs to a group of medicines called muscle relaxants. It is used to relax muscles during surgery.

Atracurium is used:

- during surgery, other procedures and in intensive care
- during general anaesthesia to ease tracheal intubation (a tube into the windpipe) and controlled ventilation

2. BEFORE YOU RECEIVE ATRACURIUM

You should NOT be given Atracurium if

- you are **allergic** (hypersensitive) to **Atracurium** or **any of the other ingredients** (see list of ingredients in Section 6). An allergic reaction may include rash, itching, difficulty of breathing or swelling of the face, lips, throat or tongue. You may know this from earlier experience.

Atracurium must not be given together with a blood transfusion, only via a separate infusion line.

Take special care with Atracurium

Before you receive Atracurium, tell your doctor if you have:

- a disease that affects the muscles and/or their nervous control (neuromuscular disease

such as myasthenia gravis or Eaton-Lambert syndrome)

- a severe electrolyte disorder
- cancer spread widely from a primary source (carcinomatosis)
- a sensitivity to histamine
- asthma-like symptoms (a history of allergy, asthma or bronchospasm)
- burns
- lack of adequate circulatory filling (hypovolaemia)

Using other medicines

Please tell your doctor or pharmacist if you are taking, or have recently taken, any other medicines, including medicines you can get without a prescription. This is especially important with the following medicines as they may interact with your Atracurium:

- antibiotics (e.g. aminoglycosides, polymyxins, spectinomycin, tetracyclines, lincomycin, clindamycin and vancomycin)
- antiarrhythmic medicines (used to control the rhythm of the heart e.g. lidocaine, procainamide, quinidine)
- diuretics (water tablets) (e.g. furosemide, thiazides, acetazolamide and mannitol)
- medicines used to control blood pressure, angina or other heart problems (e.g. propranolol, oxprenolol, diltiazem, nifedipine and verapamil)
- antiepileptic medicines (e.g. carbamazepine, phenytoin)
- drugs used to treat rheumatism (e.g. chloroquine, d-penicillamine)
- corticosteroids (treatment of inflammation)
- trimetaphan, hexamethonium (used to lower blood pressure during surgery)
- dantrolene (a muscle relaxant)
- magnesium sulphate
- ketamine (an anaesthetic drug)

- lithium, chlorpromazine (treatment of mental illness)
- quinine (treatment of malaria or leg cramps)

It may still be all right for you to be given Atracurium and your doctor will be able to decide what is suitable for you.

Children

The use of Atracurium is not recommended in neonates (children under the age of one month). In the case of necessary treatment in newborn or premature newborn the dose has to be significantly lowered. Ask your doctor if you have any further questions.

Pregnancy and breast-feeding

Atracurium should not be given to pregnant women unless medically justified. Mothers should stop breast-feeding for 24 hours after receiving Atracurium. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

After you have been given Atracurium, you must not drive, operate machinery, or work in dangerous situations. You should not go home alone and should **not drink alcohol until fully recovered**.

3. HOW TO USE ATRACURIUM

Atracurium must only be given by an experienced doctor under carefully controlled conditions.

Dosage

Atracurium is used during procedures that require that the patient is fully anaesthetized (unconscious), or heavily sedated.

The dosing will be worked out by the doctor. Atracurium must be given only by injection directly into a vein. Atracurium must not be injected into a muscle.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Atracurium can cause side effects, although not everybody gets them.

The following side effects have been reported:

Common (in less than 1 in 10 patients, but more than 1 in 100 patients)

- tachycardia (rapid heartbeat)
- temporary hypotension (low blood pressure)
- wheezing
- bronchospasm (asthma-like symptoms)
- skin flushing
- urticaria (nettle rash)

Very rare (in less than 1 in 10 000 patients, including isolated cases)

- myasthenia and/or myopathy (weak or non-working muscles)
- severe allergic reactions including shock,

circulatory failure and heart attack in patients receiving atracurium with one or more anaesthetic drugs

- seizures (fits) when taken with other drugs in at-risk patients
- laryngospasm (spasm of the vocal cords)

If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE ATRACURIUM

Keep out of the sight and reach of children.

Your doctor and pharmacist are responsible for the correct storage, use and disposal of Atracurium. It should be stored at 2°C-8°C. Do not freeze. Keep the container in the outer carton in order to protect from light.

Do not use Atracurium after the expiry date which is stated on the carton and label after "EXP.". The expiry date refers to the last day of that month.

Do not use Atracurium if you notice the solution is not clear, colourless and free of particles or if the container is damaged.

6. FURTHER INFORMATION

What Atracurium contains

The active substance is atracurium besilate.

1 ml of Atracurium contains 10 mg of atracurium besilate.

The other ingredients are Water for injections and Benzenesulfonic acid.

What Atracurium looks like and the content of the pack

Atracurium is a clear and colourless solution for injection or infusion.

3 ml or 5 ml clear glass ampoules

Box of 5 ampoules with 2.5 or 5 ml

Box of 10 ampoules with 2.5 or 5 ml

Box of 5 x 10 ampoules with 2.5 or 5 ml

Not all pack sizes may be marketed.

Marketing Authorisation Holder

hameln pharmaceuticals gmbh
Langes Feld 13
31789 Hameln
Germany

Distributor

hameln pharmaceuticals ltd
Gloucester
United Kingdom

For any information about this medicine, please contact the Distributor.

This leaflet was last approved May 2008