Package leaflet: Information for the patient

Atracurium Besilate 10 mg/ml Solution for Injection/Infusion

atracurium besilate

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, ask your doctor or nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Atracurium Besilate is and what it is used for

Atracurium Besilate belongs to a group of medicines called muscle relaxants.
Atracurium Besilate is used during surgery to relax muscles and to assist with inserting a breathing tube and with artificial breathing. It is also used to help with artificial breathing at patients in intensive care units.

2. What you need to know before you receive Atracurium Besilate

Atracurium Besilate cannot be administered:
- if you are allergic to atracurium besilate, cisatracurium or any of the other ingredients of this medicine (listed in section 6).

If you think that this applies to you talk to your doctor before Atracurium Besilate is administered to you.

Warnings and precautions
Talk to your doctor or nurse before using Atracurium Besilate
- if you have an allergy or bronchial asthma;
- if you have ever had an allergic reaction to other medicines similar to Atracurium Besilate that blocks the transmission of impulses between a nerve and muscle;
- if you suffer from muscle weakness, tiredness or difficulty in coordination of movements (*myasthenia gravis*);
- if you suffer from a neuromuscular disease;
- if you have a heart disease or you are sensitive to a drop in blood pressure;
- if you have severe electrolyte disorders (unusual levels of ions such as sodium, potassium or chloride in your blood);
- if you have recently suffered severe burns that required medical attention.

If you think that any of the above can apply to you, talk to your doctor.

Children
This medicine is not intended for use in infants up to1 month of age.

Other medicines and Atracurium Besilate
Tell your doctor if you are taking, have recently taken or might take any other medicines. This also applies to medicines available without a prescription.

Some medicines may influence the effects of Atracurium Besilate. Tell your doctor if you are taking any of the following:
- anaesthetics (used to reduce consciousness and pain during surgical procedure), such as halothane, isoflurane, enflurane or ketamine;
- antibiotics (used to treat infections), such as aminoglycosides, polymyxins, spectinomycin, tetracyclines, lincomycin and clindamycin;
- anti-arrhythmic drugs (used to treat heart rhythm disorders), such as propranolol, oxprenolol, calcium channel blockers, lidocaine, procainamide and quinidine;
- water pills (diuretics), such as furosemide, mannitol, thiazide diuretics and acetazolamide;
- magnesium salts (used to prevent low levels of magnesium in the body);
- medicines used to treat mental disorders, such as lithium or chlorpromazine;
- medicines used to treat high blood pressure (hypertension), such as trimetaphan and hexamethonium;
- medicines used to treat joint inflammation (anti-rheumatic drugs), such as chloroquine and penicillamine;
- medicines used to treat Alzheimer´s disease, such as donepezil;
- steroids (used to treat inflammations or asthma), such as prednisolone;
- medicines used to treat fits (epilepsy), such as phenytoin.

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 administration of this medicine. Your doctor will consider the benefit of your therapy against the risk of administration of Atracurium Besilate for your child.

Atracurium Besilate can be used to maintain relaxation of muscle tension during caesarean section.

Driving and using machines
Atracurium Besilate has major influence on the ability to drive and use machines. Ask the doctor for advice on when it is safe to drive and use machines again.
Do not drive or use machines if you feel unwell.

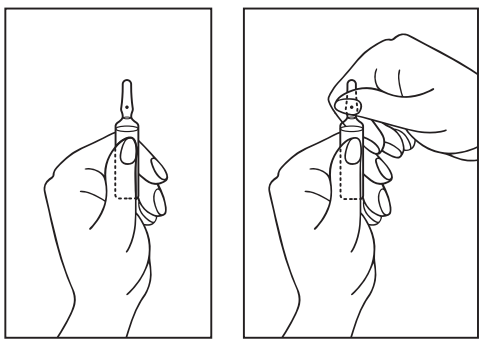
3. How to use Atracurium Besilate

Atracurium Besilate is used during procedures which require you to be anaesthetised (unconscious) or heavily sedated. It will be always administered under the supervision of an experienced doctor.

What quantity is administered
Your doctor will determine the correct dose of Atracurium Besilate depending on:
- your body weight;
- the extent and duration of required relaxation of muscle tension;
- your expected response (reaction) to the drug administration.

How Atracurium Besilate is administered
Atracurium Besilate will be given to you by a single injection into your vein or as a continuous infusion (usually using an infusion pump) into your vein. In this case the medicine is given slowly over a certain period of time.

Instruction of ampoule opening:
1) Turn the ampoule with coloured point up. If there is any solution in the upper part of the ampoule, gently tap with your finger to get all the solution to the lower part of the ampoule.
2) Use both hands to open; while holding the lower part of the ampoule in one hand, use the other hand to break off the upper part of the ampoule in the direction away from the coloured point (see the pictures below).



Use in children
Infants aged up to 1 month should not receive this medicine.

If you are given more Atracurium Besilate than you should
This medicine will only be used by doctors who are appropriately skilled in its administration. As this medicine will be given to you whilst you are in hospital it is unlikely that you will be given too little or too much, however tell your doctor or a healthcare professional immediately if you have any concerns. In the case of administration of too large dose the appropriate measures will be implemented immediately.

The following information is intended for healthcare professionals only:

For single use only. Once opened, the product should be used immediately.

From a microbiological point of view, unless the method of dilution precludes the risk of microbial contamination, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user.

Atracurium besilate is inactivated by high pH, thus it must not be mixed in the same syringe with solutions of thiopental or any other alkaline solutions.

After injecting Atracurium Besilate into a small vein, physiological saline solution should be flushed through the vein. When other medicines are administered through the same indwelling needle or cannula as Atracurium Besilate, it is necessary to rinse it with a sufficient volume of physiological saline after administration of each medicine.

Atracurium Besilate is a hypotonic solution and thus it must not be administered into the same venous access as a blood transfusion.

Atracurium Besilate is compatible with the following solutions for infusion.

4. Possible side effects

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

If any of the following happen, tell the doctor immediately:
- severe allergic reaction – you may get a sudden itchy rash (hives), swelling of the hands, feet, ankles, face, lips, mouth or throat (which may cause difficulty in swallowing or breathing), and you may feel you are going to faint;
- shock;
- heart failure;
- cardiac arrest.

The above are very rare, serious side effects. You may need urgent medical attention.

If you experience any of the following tell your doctor as soon as possible:

Common side effects (may affect up to 1 in 10 people):
- low blood pressure (hypotension), usually mild and transient;
- skin redness.

Uncommon side effects (may affect up to 1 in 100 people):
- difficulty in breathing and whistling (bronchospasm).

Not known (frequency cannot be estimated from the available data):
- convulsions;
- muscle disorders (*myopathy*), muscle weakness.

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:
United Kingdom (Northern Ireland): Yellow Card Scheme. Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.
Ireland: HPRA Pharmacovigilance, Website: www.hpra.ie
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Atracurium Besilate

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 label and on the carton after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2 °C – 8 °C). Do not freeze.
Store in the original package in order to protect from light.

For single use only. Once opened, the product should be used immediately.

The solution is to be visually inspected prior to use. Only clear solutions practically free from particles should be used.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Atracurium Besilate contains

- The active substance is atracurium besilate.
1 ml of solution contains 10 mg of atracurium besilate.
Each ampoule (2.5 ml) contains 25 mg of atracurium besilate.
Each ampoule (5 ml) contains 50 mg of atracurium besilate.

- The other ingredients are benzenesulfonic acid (for pH adjustment), water for injections.

What Atracurium Besilate looks like and contents of the pack
Clear colourless or yellowish solution for injection/infusion, free from visible particles.

2.5 ml or 5.0 ml of solution filled in 5.0 ml type I colourless glass ampoules.
Ampoules are packed in a PVC liner. Liner is placed into an outer carton.

Pack size: 1 or 5 ampoules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
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This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Bulgaria	Atracurium Kalceks 10 mg/ml инжекционен/инфузионен разтвор
Belgium	Atracurium Kalceks 10 mg/ml solution injectable/pour perfusion Atracurium Kalceks 10 mg/ml oplossing voor injectie/infusie Atracurium Kalceks 10 mg/ml Injektions-/Infusionslösung
Czech Republic	Atracurium Kalceks
Estonia	Atracurium besilate Kalceks
France	ATRACURIUM KALCEKS 10 mg/ml, solution injectable/pour perfusion
Hungary	Atracurium besilate Kalceks 10 mg/ml oldatos injekció/infúzió
Ireland	Atracurium Besilate 10 mg/ml Solution for Injection/Infusion
Latvia	Atracurium besilate Kalceks 10 mg/ml šķīdums injekcijām/infūzijām
Lithuania	Atracurium besilate Kalceks 10 mg/ml injekcinis ar infuzinis tirpalas
Malta	Atracurium Kalceks 10 mg/ml solution for injection/infusion
The Netherlands	Atracurium Kalceks 10 mg/ml oplossing voor injectie/infusie
Poland	Atracurium Kalceks
Romania	Atracurium Kalceks 10 mg/ml soluție injectabilă/perfuzabilă
Slovakia	Atracurium Kalceks 10 mg/ml injekčný/infúzny roztok
Spain	Besilato de Atracurio Kalceks 10 mg/ml solución inyectable y para perfusión EFG
Sweden	Atracurium Kalceks 10 mg/ml injektions-/infusionsvätska, lösning
United Kingdom (Northern Ireland)	Atracurium besilate 10 mg/ml solution for injection/infusion

This leaflet was last revised in 08/2022

Infusion solution	*Period of stability*
Sodium chloride intravenous infusion (9 mg/ml)	24 hours
Glucose intravenous infusion (50 mg/ml)	8 hours
Ringer intravenous infusion	8 hours
Sodium chloride (1.8 mg/ml) and glucose (40 mg/ml) intravenous infusion	8 hours
Ringer lactate intravenous infusion	4 hours

When diluted in these solutions to give atracurium besilate concentrations of 0.5 mg/ml and above, the resultant solutions will be stable in daylight for the stated periods at temperatures of up to 25 °C.