

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, 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

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2. What you need to know before you use Atracurium Besilate solution for injection/infusion
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1. What Atracurium Besilate solution for injection/infusion is and what it is used for

Atracurium Besilate solution for injection/infusion contains the active substance atracurium besilate. Atracurium Besilate solution for injection/infusion belongs to a group of medicines called muscle relaxants.

Atracurium Besilate solution for injection/infusion 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 in patients in intensive care.

Atracurium Besilate solution for injection/infusion is used to treat adults, and babies, children and adolescents aged over 1 month to 18 years.

2. What you need to know before you use Atracurium Besilate solution for injection/infusion

Do not use Atracurium Besilate solution for injection/infusion

- if you or your child are allergic to atracurium besilate or any of the other ingredients of this medicine (listed in section 6).
- if you or your child are allergic to cisatracurium.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Atracurium Besilate solution for injection/infusion if you or your child:

- have had **allergic reactions to other muscle relaxants** (see section **Do not use Atracurium Besilate solution for injection/infusion**)
- have **problems with your lungs**
- have a **history of allergy or asthma**
- suffer from **myasthenia gravis, Eaton-Lambert syndrome or other neuromuscular diseases** (these diseases may result in muscle weakness)
- have **severe electrolyte disorders** (unusual levels of ions such as sodium, potassium or chloride in your blood)

- have **heart or circulation problems**
- are **suffering from burns**
- have a **history of seizures**
- have a **head injury or brain disease**

Other medicines and Atracurium Besilate solution for injection/infusion

Tell your doctor, pharmacist or nurse if you or your child are using, have recently used or might use any other medicines.

Some medicines are known to interact with Atracurium Besilate solution for injection/infusion. Tell your doctor, pharmacist or nurse if you or your child are taking any of the following:

- **antibiotics** (e.g., aminoglycosides, polymyxins, spectinomycin, tetracyclines, lincosamides (e.g., lincomycin, clindamycin), vancomycin and telithromycin)
- **local anaesthetics** (e.g., lidocaine)
- **antiarrhythmic medicines** (used to control the rhythm of the heart) (e.g., lidocaine, procainamide, quinidine)
- **diuretics** (water tablets) (e.g., furosemide, thiazides, acetazolamide, mannitol)
- **medicines used to control blood pressure or angina or other heart problems** (e.g., propranolol, oxprenolol, diltiazem, nifedipine, nifedipine, trimetaphan, hexamethonium and verapamil)
- **antiepileptic medicines** (e.g., carbamazepine, phenytoin)
- **medicines used to treat rheumatism** (e.g., chloroquine, d-penicillamine)
- **corticosteroids** administered into your vein (used in the treatment of allergic emergencies, severe asthma and septic shock)
- **inhalation anaesthetics** (drugs to put you to sleep) (e.g., isoflurane, desflurane, sevoflurane and enflurane anaesthesia, halothane)
- **medicines used to treat Alzheimer's disease** (e.g., donepezil)
- others you may recognise by name (e.g., dantrolene (used in anaesthesia), magnesium sulphate (used to treat eclampsia and pre-eclampsia in pregnant women and some heart problems), ketamine (used in anaesthesia), lithium (used to treat bipolar disorder), quinine (used to treat malaria and leg cramps) and chlorpromazine (used to treat some psychiatric disorders and nausea)

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 using this medicine.

Atracurium Besilate solution for injection/infusion should not be used during the first three months of pregnancy. It will not be used during the second and third trimesters unless your doctor advises that it is necessary. Atracurium Besilate solution for injection/infusion can be used during a caesarean section.

Do not breast-feed within 24 hours of being given Atracurium Besilate solution for injection/infusion.

Driving and using machines

Do not drive or use machines within 24 hours after full recovery from Atracurium Besilate solution for injection/infusion.

3. How to use Atracurium Besilate solution for injection/infusion

Atracurium Besilate solution for injection/infusion is used during procedures which require you or your child to be anaesthetised (unconscious) or heavily sedated. The amount given to you

will depend upon the length of time you will be unconscious or heavily sedated and your body weight.

The recommended dose is approximately 0.3 – 0.6 mg/kg of body weight initially, followed by a reduced dose at specific intervals. This standard dose will be given to babies, children, adolescents and adults. The rate this medicine is administered may vary depending on your or your child's age and if you or your child suffer from any heart problems. You or your child will be monitored during use with this medicine, and the dose will be adjusted if necessary.

Atracurium Besilate solution for injection/infusion will be given to you or your child by an injection into a vein.

Use in children

Children less than 1 month old should not have this medicine.

If you are given more Atracurium Besilate solution for injection/infusion than you should

Atracurium Besilate solution for injection/infusion will only be used by doctors or other healthcare professionals who are appropriately skilled in its administration. As this medicine will be given to you or your child whilst you are in hospital it is unlikely that you or your child will be given too little or too much, however tell your doctor or a healthcare professional immediately if you have any concerns.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, Atracurium Besilate solution for injection/infusion can cause side effects, although not everybody gets them.

If any of the following happens, tell the doctor or other healthcare professional immediately:

- sudden severe allergic reaction with breathing difficulty, swelling, lightheadedness, fast heartbeat, sweating and loss of consciousness. Other symptoms of severe allergic reactions may include cardiac arrest (heart stops beating), shock (a steep fall in blood pressure) and heart failure (when the heart does not pump blood as well as it should).

The above are rare or very rare serious side effects. You or your child may need urgent medical attention.

If you or your child experience any of the following tell your doctor or other healthcare professional as soon as possible:

Common side effects (may affect up to 1 in 10 people)

- rapid heart beat
- slow heart beat
- high blood pressure (hypertension)
- low blood pressure (hypotension)
- flushing of the skin
- wheezing
- localised rash or itching of the skin
- soreness at the injection site

Uncommon side effects (may affect up to 1 in 100 people)

- difficulty breathing

- generalised redness of the skin
- hives

Rare side effects (may affect up to 1 in 1,000 people)

- shortness of breath
- spasm of the vocal cords
- rapid swelling under the skin (angioneurotic oedema)
- itchy rash

Very rare side effects (may affect up to 1 in 10,000 people)

- low blood oxygen level (hypoxemia)

Not known (frequency cannot be estimated from the available data)

- increased mucous secretions in the lungs
- prolonged action of the medicine

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

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Atracurium Besilate solution for injection/infusion

Keep this medicine out of the sight and reach of children.

Do not use Atracurium Besilate solution for injection/infusion after the expiry date which is stated on the vial label and carton.

The vials should be stored in a refrigerator (2 – 8 °C) but not frozen.

The vials should be kept in the outer carton (in order to protect from light).

6. Contents of the pack and other information

What Atracurium Besilate solution for injection/infusion contains

The active substance is atracurium besilate.

The other ingredients are benzenesulphonic acid and Water for Injections.

What Atracurium Besilate solution for injection/infusion looks like and contents of the pack

This medicinal product is a solution for injection/infusion (a solution which can be given as an injection/infusion). It is a clear, colourless or faint yellow solution. Each millilitre (mL) of solution contains 10 milligrams (mg) of atracurium besilate.

This medicine is presented in glass containers (vials). The 5 mL vial is available in packs containing 10 vials and the 25 mL vial is available in packs containing 1 vial.

Not all presentations may be marketed.

Marketing Authorisation Holder

Hospira UK Limited
Walton Oaks
Walton-On-The-Hill
Dorking Road
Tadworth
Surrey
KT20 7NS

Manufacturer(s)

Hospira UK Limited
Horizon
Honey Lane
Hurley
Maidenhead
SL6 6RJ
UK

Pfizer Service Company BV
Hoge Wei 10
1930 Zaventem
Belgium

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The following information is intended for healthcare professionals only:

Handling and preparation:

Do not use if cloudiness or precipitate is observed.

Atracurium Besilate solution for injection/infusion has an acid pH and therefore should not be mixed with alkaline solutions (e.g., barbiturate solutions) in the same syringe or administered simultaneously during intravenous infusion through the same needle.

To avoid distress to the patient, Atracurium Besilate solution for injection/infusion should not be administered before unconsciousness has been induced.

Atracurium Besilate solution for injection/infusion may be administered as an intravenous injection or infusion.

Do not give Atracurium Besilate solution for injection/infusion intramuscularly since this may result in tissue irritation and there are no clinical data to support this route of administration.

When a small vein is selected as the injection site, Atracurium Besilate solution for injection/infusion should be flushed through the vein with physiological saline after injection.

When other anaesthetic drugs are administered through the same indwelling needle or cannula as Atracurium Besilate solution for injection/infusion, it is important that each drug is flushed through with an adequate volume of physiological saline.

Atracurium Besilate solution for injection/infusion is hypotonic and must not be applied into the infusion line of a blood transfusion.

Where an infusion is required, infusion solutions of Atracurium Besilate solution for injection/infusion may be prepared by admixing Atracurium Besilate solution for injection/infusion with an appropriate diluent (see below) to give an atracurium besilate concentration of 0.5 mg/mL to 5 mg/mL.

Atracurium Besilate solution for injection/infusion diluted to 0.5 mg/mL with the following infusion solutions, and stored at 30 °C protected from light, was shown to be stable for the times stated below.

| Infusion Solution | Period of stability (hours) |
|--|------------------------------------|
| Sodium Chloride 0.9% Intravenous Infusion | 24 |
| Glucose 5% Intravenous Infusion | 24 |
| Glucose 4% and Sodium Chloride 0.18% Intravenous Infusion | 24 |
| Ringer's Injection USP | 24 |
| Compound Sodium Lactate Intravenous Infusion (Hartmann's Solution for Injection) | 4 |

Atracurium Besilate solution for injection/infusion diluted to 5 mg/mL with the following infusion solutions, and stored at 30 °C protected from light in 50 mL plastic syringes, was shown to be stable for the times stated below.

| Infusion Solution | Period of stability (hours) |
|--|------------------------------------|
| Sodium Chloride 0.9% Intravenous Infusion | 24 |
| Glucose 5% Intravenous Infusion | 24 |
| Glucose 4% and Sodium Chloride 0.18% Intravenous Infusion | 24 |
| Ringer's Injection USP | 24 |
| Compound Sodium Lactate Intravenous Infusion (Hartmann's Solution for Injection) | 8 |

However, from a microbiological point of view, the product should be used immediately. If not used immediately, in use storage times and conditions prior to use are the responsibility of the user.

The anaesthesiologists or other practitioners must be prepared to assist or control ventilation, and anticholinesterase agents should be immediately available for reversal of neuromuscular blockade.

The potential for histamine release exists in susceptible patients during administration of Atracurium Besilate solution for injection/infusion. Caution should be exercised in patients with a history suggestive of an increased sensitivity to the effects of histamine.

Disposal:

Discard residue immediately after use.