PACKAGE LEAFLET: INFORMATION FOR THE USER

Atracurium Besilate 10 mg/ml Solution for Injection
The active substance is atracurium besilate

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

In this leaflet:

1. What Atracurium Besilate Solution for Injection is and what it is used for
2. What you need to know before you use Atracurium Besilate Solution for Injection
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1. WHAT ATRACURIUM BESILATE SOLUTION FOR INJECTION IS AND WHAT IT IS USED FOR

Atracurium Besilate Solution for Injection is a medicine which acts as a muscle relaxant.

Atracurium Besilate Solution for Injection 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.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE ATRACURIUM BESILATE SOLUTION FOR INJECTION

Do not use Atracurium Besilate Solution for Injection
- **if you are allergic (hypersensitive) to atracurium besilate** or any of the other ingredients of this drug (see section 6)

Warnings and precautions
Talk to your doctor, pharmacist or nurse before using Atracurium Besilate Solution for Injection if you
- are pregnant or breast-feeding (see Pregnancy and breast-feeding)
- have **heart or circulation problems**
- have **problems with your lungs**
- have a **history of allergy or asthma**
- suffer from **myasthenia gravis, Eaton-Lambert syndrome or other neuromuscular diseases** (these may result in muscle weakness)
- have **severe electrolyte disorders** (unusual levels of ions such as sodium, potassium or chloride in your blood)
- are **suffering from burns**
- have had **allergic reactions to other muscle relaxants** (e.g. curares)

Using other medicines
Please tell your doctor, pharmacist or nurse if you are using or have recently used any other medicines, including medicines obtained without a prescription.

Some medicines are known to interact with atracurium besilate, tell your doctor if you are taking any of the following:

- **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. frusemide, thiazides, acetazolamide, mannitol)
- **medicines used to control blood pressure or angina or other heart problems** (e.g. propranolol, oxprenolol, diltiazem, nicardipine, nifedipine, trimetaphan, hexamethonium and verapamil)
- **antiepileptic medicines** (e.g. carbamazepine, phenytoin)
- **drugs 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)
- 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 taking this medicine.

Atracurium besilate 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 can be used during a caesarean section.

Your baby would be closely monitored if you breast-feed within 24 hours of being given atracurium besilate.

Driving and using machines
Do not drive or use machines within 24 hours of being given atracurium besilate.

3. HOW TO USE ATRACURIUM BESILATE SOLUTION FOR INJECTION

Atracurium besilate is used during procedures which require you 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.

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

Atracurium besilate will be given to you by an injection into a vein.

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

If you are given more Atracurium Besilate Solution for Injection than you should be given
Atracurium besilate 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.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Atracurium Besilate Solution for Injection 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
- seizures (fits)
- shock
- heart failure
- cardiac arrest

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

Uncommon side effects (may affect up to 1 in 100 people)
- difficulty breathing
- generalised rash or 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)
- itching

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)
- prolonged therapeutic action of the medicine

- insufficient therapeutic action of the medicine
- increased mucous secretions in the lungs
- muscle weakness/tiredness or difficulty controlling your muscles

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

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

Keep out of the sight and reach of children.

Do not use Atracurium Besilate Solution for Injection 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 contains
The active substance is atracurium besilate

The other ingredients are benzenesulphonic acid and Water for Injections

What Atracurium Besilate Solution for Injection looks like and contents of the pack

This medicinal product is a solution for injection (a solution which can be given as an injection). 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 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
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Manufacturer(s)

Hospira UK Limited

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Pfizer Service Company BV
Hoge Wei 10
1930 Zaventem
Belgium

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The following information is intended for medical or healthcare professionals only:

Handling and preparation:
Do not use if cloudiness or precipitate is observed.

Atracurium Besilate Solution for Injection 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 Injection should not be administered before unconsciousness has been induced.

Atracurium Besilate Solution for Injection may be administered as an intravenous injection or infusion.

Do not give Atracurium besilate injection 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 Injection should be flushed through the vein with physiological saline after injection.

Atracurium Besilate Injection is hypotonic and must not be applied into the infusion line of a blood transfusion.

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

Atracurium Besilate Injection 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**
Sodium Chloride 0.9% Intravenous Infusion	24 hours
Glucose 5% Intravenous Infusion	24 hours
Glucose 4% and Sodium Chloride 0.18% Intravenous Infusion	24 hours

Ringer's Injection USP	24 hours
Compound Sodium Lactate Intravenous Infusion (Hartmann's Solution for Injection)	4 hours

Atracurium Besilate Injection 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**
Sodium Chloride 0.9% Intravenous Infusion	24 hours
Glucose 5% Intravenous Infusion	24 hours
Glucose 4% and Sodium Chloride 0.18% Intravenous Infusion	24 hours
Ringer's Injection USP	24 hours
Compound Sodium Lactate Intravenous Infusion (Hartmann's Solution for Injection)	8 hours

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 clinician must be prepared to assist of 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. 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.