Product + Component:	Atracurium Hikma
Identifier:	
Country:	United Kingdom / Ireland
Dimensions:	160 x 290 mm
Scale:	1:1
Circular for Corrections:	05
Date:	25.06.2014
Colours:	Black
Front/Reverse:	Front
Fonts:	Frutiger

Front

175 mm

1 mm 9 mm 1 mm

315 mm

PACKAGE LEAFLET: INFORMATION FOR THE USER

Atracurium 10 mg/ml Solution for injection or infusion

Atracurium besilate

Read all of this leaflet carefully before you start receiving Atracurium.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

In this leaflet

1. WHAT ATRACURIUM IS AND WHAT IT IS USED FOR

The active substance in Atracurium is atracurium besilate. This belongs to a group of medicines called muscle relaxants.

Atracurium is used:
- to relax muscles during operations on adults and children over 1 month of age
- to help insert a tube into the windpipe (tracheal intubation), if a person needs help to breathe
- to relax the muscles of adults in intensive care

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ATRACURIUM

Do not take Atracurium if:
- you are allergic to atracurium besilate, any other muscle relaxant or any of the other ingredients in Atracurium (listed in Section 6)
- you have reacted badly to an anaesthetic before.

Do not take Atracurium if any of the above applies to you.
If you are not sure, talk to your doctor, nurse or pharmacist before you have Atracurium.

Warnings and precautions
Talk to your doctor or pharmacist before receiving Atracurium.
- you have muscle weakness, tiredness or difficulty in co-ordinating your movements (myasthenia gravis)
- you have a neuromuscular disease, such as a muscle wasting disease, paralysis, motor neurone disease or cerebral palsy
- you have a burn which requires medical treatment
- you have ever had an allergic reaction to any muscle relaxant which was given as part of an operation
- you have a history of sensitivity to histamine. In particular, spasm of the airways may occur if you have a history of allergy or asthma

Children and adolescents
The dosage in children over the age of one month is similar to that in adults on a bodyweight basis.
The use of Atracurium is not recommended in neonates since there are insufficient data available.

Other medicines and Atracurium
Tell your doctor, nurse or pharmacist if you are receiving or have recently taken any other medicines. This includes medicines obtained without a prescription, including herbal medicines.
This is because these medicines can affect how well Atracurium works or can cause side effects.

In particular tell your doctor, nurse or pharmacist if you are receiving any of the following:
- anaesthetics (used to reduce sensation and pain during surgical procedures)
- antibiotics (used to treat infections)
- medicines for heart conditions
- medicines for high blood pressure
- water tablets (diuretics), such as furosemide
- medicines for fits (epilepsy), such as phenytoin or carbamazepine
- medicines containing magnesium, such as those to treat indigestion and heart burn
- drugs for Alzheimer's disease (anticholinesterases e.g. donepezil)
- medicines for mental illness, such as lithium
- medicines for inflammation of the joints, such as chloroquine or D-penicillamine
- steroids

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 receiving this medicine.

Atracurium should only be administered during pregnancy after careful risk-benefit assessment.
Atracurium can be used during a caesarean section.

As precaution restart breast feeding 24 hours after administration of Atracurium.

Driving and using machines
Do not drive or use machines in exposed situations after anesthesia.

3. HOW TO TAKE ATRACURIUM

How Atracurium is given
Atracurium will be administered to you by a healthcare professional.
Atracurium can be given:
- as a single injection into your vein (intravenous bolus injection)
- as a continuous infusion into your vein.

This is where the drug is slowly given to you over a long period of time.

The following information is intended for healthcare professionals only:

Atracurium 10 mg/ml Solution for injection or infusion

Atracurium besilate

Therapeutic indications
Atracurium is a highly selective, competitive or non-depolarising neuromuscular blocking agent. It is used as an adjunct to general anaesthesia or sedation in the intensive care unit (ICU), to relax skeletal muscles, and to facilitate tracheal intubation and mechanical ventilation.

Posology and method of administration
Administration by injection in adults
Route of administration: Intravenous injection or continuous infusion.

The dosage range recommended for adults is 0.3 to 0.6 mg/kg (depending on the duration of full block required) and will provide adequate relaxation for about 15 to 35 minutes.

Endotracheal intubation can usually be accomplished within 90 seconds from the intravenous injection of 0.5 to 0.6 mg/kg.

Full block can be prolonged with supplementary doses of 0.1 to 0.2 mg/kg as required. Successive supplementary dosing does not give rise to accumulation of neuromuscular blocking effect.
Spontaneous recovery from the end of full block occurs in about 35 minutes as measured by the restoration of the tetanic response to 95% of normal neuromuscular function.

The neuromuscular block produced by Atracurium can be rapidly reversed by standard doses of anticholinesterase agents, such as neostigmine and edrophonium, accompanied or preceded by atropine, with no evidence of recurarisation.

Administration by infusion in adults
After an initial bolus dose of 0.3 to 0.6 mg/kg, Atracurium can be used to maintain neuromuscular block during long surgical procedures by administration as a continuous infusion at rates of 0.3 to 0.6 mg/kg/hour.

Atracurium can be administered by infusion during cardiopulmonary bypass surgery at the recommended infusion rates. Induced hypothermia to a body temperature of 25° to 26°C reduces the rate of inactivation of atracurium, therefore full neuromuscular block may be maintained by approximately half the original infusion rate at these low temperatures.

Children
The dosage in children over the age of one month is similar to that in adults on a bodyweight basis.

Neonates
The use of Atracurium is not recommended in neonates since there are insufficient data available (see section 5.1).

Elderly
Atracurium may be used at standard dosage in elderly patients. It is recommended, however, that the initial dose be at the lower end of the range and that it be administered slowly.

Laetus Barcode

35 mm

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Your doctor will decide the way you are given the drug and the dose you will receive. It will depend on:
- your body weight
- the amount and duration of muscle relaxation required
- your expected response to the medicine.

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

If you receive more Atracurium than you should
Atracurium will always be given under carefully controlled conditions. However, if you think that you have been given more than you should tell your doctor or nurse immediately.

4. POSSIBLE SIDE EFFECTS
Like all medicines, Atracurium can cause side effects, although not everybody gets them.
The following effects may happen with this medicine:

Allergic reactions
If you have an allergic reaction, tell your doctor or nurse straight away. The signs may include:

Common side effects (affects less than 1 person in 10)
- decrease in blood pressure
- rash or redness of your skin

Uncommon side effects (affects less than 1 person in 100)
- wheezing or coughing

Rare side effects (affects less than 1 person in 1000)
- a lumpy skin rash or 'hives' anywhere on your body

Very Rare side effects (affects less than 1 person in 10,000)
- sudden wheeziness, chest pain or chest tightness
- decrease in heart rate
- shock, circulatory failure, cardiac arrest
- swelling of your eyelids, face, lips, mouth or tongue

Very rarely a severe allergic reaction can occur when given one or more anaesthetic agent.

Other side effects (unknown frequency) that you may experience are:
- seizures
- muscle weakness

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

If you get any side effects, talk to your doctor, this includes any possible side effects not listed in this leaflet you can also report side effects directly for the following contacts. By reporting side effects you can help provide more information on the safety of this medicine.

IMB Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.imb.ie
e-mail: imbpharmacovigilance@imb.ie

United Kingdom
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard

Reduced renal and/or hepatic function
Atracurium may be used at standard dosage at all levels of renal or hepatic function, including end stage failure.

Cardiovascular disease
In patients with clinically significant cardiovascular disease, the initial dose of Atracurium should be administered over a period of 60 seconds.

Intensive care unit (ICU)
After an optional initial bolus dose of Atracurium of 0.3 to 0.6 mg/kg, Atracurium can be used to maintain neuromuscular block by administering a continuous infusion at rates of between 11 and 13 micrograms/kg/min (0.65 to 0.78 mg/kg/hr). There may be wide inter-patient variability in dosage requirements and these may increase or decrease with time. Infusion rates as low as 4.5 microgram/kg/min (0.27 mg/kg/hr) or as high as 29.5 microgram/kg/min (1.77 mg/kg/hr) are required in some patients.

The rate of spontaneous recovery from neuromuscular block after infusion of Atracurium in ICU patients is independent of the duration of administration.

Spontaneous recovery to a train-of-four ratio >0.75 (the ratio of the height of the fourth to the first twitch in a train-of-four) can be expected to occur in approximately 60 minutes. A range of 32 to 108 minutes has been observed in clinical trials.

Monitoring
In common with all neuromuscular blocking agents, monitoring of neuromuscular function is recommended during the use of Atracurium in order to individualise dosage requirements.

5. HOW TO STORE ATRACURIUM
Do not use Atracurium after the expiry date which is stated on the label and carton, after EXP. The expiry date refers to the last day of that month.

Keep out of the sight and reach of children.

Store in a refrigerator between 2 and 8°C.

Do not freeze.

Keep the container in the outer carton in order to protect from the light.

Do not use this medicine if you notice an unclear solution and extraneous particles or if the container is damaged.

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. FURTHER INFORMATION
What Atracurium contains
- The active substance of Atracurium is atracurium besilate.
- The other ingredients for Atracurium are: benzenesulfonic acid, water for injections

1 ml solution contains 10 mg of atracurium besilate.

Each 2.5 ml ampoule contains 25 mg of Atracurium Besilate.
Each 5 ml ampoule contains 50 mg of Atracurium Besilate.

What Atracurium looks like and contents of the pack
This medicine is clear and colourless solution.

This medicine is supplied in transparent 3 or 5 ml glass ampoule, type I. Each ampoule contains 10 mg/ml of the active ingredient atracurium besilate.

Atracurium is packed in carton boxes. Each box can contain 5 or 10 ampoules.

Marketing Authorisation Holder and Manufacturer
Hikma Farmacêutica (Portugal), S.A.
Estrada do Rio da Mó 8, 8A e 8B – Fervença
2705-906 Terrugem SNT, Portugal
Tel.: +351 219608410
Fax: +351 219615102
e-mail: geral@hikma.pt

This medicinal product is authorised in the Member States of EEA under the following names:

France:	Atracurium Hikma 10 mg/ml Solution injectable/ pour perfusion
Ireland:	Atracurium 10 mg/ml Solution for injection or infusion
Portugal:	Besilato de Atracúrio Hikma
Spain:	Atracurium Hikma 10 mg/ml Solución inyectable y para perfusión
United Kingdom:	Atracurium 10 mg/ml Solution for injection or infusion

This leaflet was last approved in 06/2014.

Shelf life
Shelf life before first opening
18 months

The solution has to be used immediately after opening the container.

Special precautions for storage
Store between 2 and 8°C. Do not freeze.

Keep the container in the outer carton in order to protect from the light.

Special precautions for disposal and other handling
Atracurium is compatible with the following infusion solutions for the times stated below:

Infusion Solution Stability	Period of
Sodium Chloride Intravenous Infusion BP (0.9% w/v)	24 hours
Glucose Intravenous Infusion BP (5% w/v)	8 hours
Ringer's Injection USP	8 hours
Sodium Chloride (0.18% w/v) and Glucose (4% w/v) Intravenous Infusion BP	8 hours
Compound Sodium Lactate Intravenous Infusion BP (Hartmann's Solution for Injection)	4 hours

When diluted in these solutions to give Atracurium 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 30°C.

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