

ATRACURIUM MEDIS® 25 mg/2,5 ml - ATRACURIUM MEDIS® 50 mg/5 ml solution for injection in vial Atracurium besilate

Read all of this leaflet carefully before you start taking 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.
- This medicine has been prescribed only for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist or nurse. This includes also any possible side effects not listed in this leaflet. See section 4

What is in this leaflet?

1. What is ATRACURIUM MEDIS solution for injection in vial and in what case is it used?
2. What you need to know before using ATRACURIUM MEDIS solution for injection in vial
3. How to take ATRACURIUM MEDIS solution for injection in vial
4. Possible side effects
5. How to store ATRACURIUM MEDIS solution for injection in vial
6. Content of the packaging and other information.

1. WHAT IS ATRACURIUM MEDIS solution for injection in vial AND IN WHICH CASE IS IT USED ?

Pharmacotherapeutic Class : Peripheral action muscle relaxants, other quaternary ammonium, ATC code : M03AC04.

ATRACURIUM MEDIS belongs to a family of medicines called muscle relaxants. Atracurium can be used to relax muscles during most general anesthesia in surgery, and to allow artificial ventilation in the intensive care unit.

2. WHAT YOU NEED TO KNOW BEFORE USING ATRACURIUM MEDIS solution for injection in vial ?

Never use ATRACURIUM MEDIS solution for injection in vial in the following cases:

- if you are allergic (hypersensitive) to atracurium or to benzene sulfonic acid.
- if you are allergic (hypersensitive) to cisatracurium

Warnings and precautions

Be cautious with ATRACURIUM MEDIS solution for injection in vial :

Atracurium should only be administered by, or under the supervision of, anesthetists or practitioners who are familiar with the use and action of curares. Adequate tracheal intubation, breathing assistance and arterial oxygenation equipment must be available.

As with all curares, monitoring of neuromuscular functions when using atracurium is recommended in order to individually adjust the needs.

Use this medication WITH CAUTION in case of :

- myasthenia gravis (excessive tendency to progressive or pushing muscle fatigue) or other neuromuscular diseases, or electrolyte abnormalities (abnormalities of water and mineral salts in the blood),
- cardiovascular failure, in this case, your doctor will administer this medicine slowly (in more than 60 seconds)
- people sensitive to a decrease in blood pressure (for example hypovolemic), (administration will be done slowly in 60 seconds),
- asthma or atopic people (allergic subjects) in this case, your doctor should give you this medicine slowly (in more than 60 seconds),
- known history of allergy to another curare.

Bronchospasms may especially occur in patients with a history of allergy or asthma.

As with all medicines in its class, ATRACURIUM MEDIS may prove to be less effective in burned patients. If used in this type of patient, the dosage may be increased if necessary depending on the extent and the time elapsed since the occurrence of the burn.

Children and adolescents

Not applicable.

Other medicines and ATRACURIUM MEDIS solution for injection in vial

It is important to tell your doctor and the anesthetist, before the injection of atracurium, about ALL the medicines currently prescribed to you, which have been recently prescribed to you, that you are currently taking without a medical prescription, or that you have taken recently without a medical prescription.

IN ORDER TO AVOID POSSIBLE INTERACTIONS BETWEEN SEVERAL MEDICINES (and in particular antibiotics, medicines for cardiac and vascular disorders, diuretics, medicines used to treat rheumatism, medicines for the nervous system, cortisone (except hydrocortisone in replacement therapy), anticonvulsants, certain medications used in the treatment of Alzheimer's disease, magnesium, lithium). ALL OTHER ONGOING OR RECENT TREATMENT MUST BE SYSTEMICALLY REPORTED TO YOUR DOCTOR OR PHARMACIST.

ATRACURIUM MEDIS, solution for injection in vial with food and drinks

Not applicable.

Pregnancy and breastfeeding

This medication will only be prescribed on the advice of your doctor.

Breastfeeding should be temporarily suspended if this medicine is used.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

After anesthesia, you should not drive or use potentially dangerous machinery until your doctor tells you when to resume these activities. It is cautious to be accompanied on your way back home.

3. HOW TO TAKE ATRACURIUM MEDIS solution for injection in vial

Dosage.

The dose of atracurium is calculated according to your weight and the intensity, mode and duration of the curarization that is sought and must be adjusted according to the neurological and muscular monitoring (neuromuscular monitoring).

Method and route of administration

This medicine will be given to you intravenously as a single injection or infusion.

If you have taken more ATRACURIUM MEDIS solution for injection in vial than you should

Signs and symptoms

The main signs of overdose are prolonged muscle paralysis and related consequences.

Treatment

It is essential to maintain artificial pulmonary ventilation until adequate spontaneous breathing is achieved. Total sedation is necessary, since alertness is not affected by atracurium. Recovery can be accelerated by the administration of anticholinesterases associated with atropine, as soon as the first signs of spontaneous recovery are observed..

If you forget to take ATRACURIUM MEDIS solution for injection in vial

Not applicable.

If you stop taking ATRACURIUM MEDIS solution for injection in vial

Not applicable.

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

4. POSSIBLE SIDE EFFECTS

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

Common side effects (affecting 1 to 10 in 100 treated patients) :

-hypotension (low blood pressure), skin redness.

Uncommon side effects (affecting 1 to 10 in 1000 treated patients) :

-bronchospasm (respiratory discomfort)

Rare side effects (affecting 1 to 10 in 10 000 treated patients) :

-Urticaria.

Very rare side effects (affecting less than 1 in 10 000 treated patient) :

-Severe allergic reactions (anaphylactic reactions and anaphylactoid reactions). Very rarely, severe anaphylactoid or anaphylactic reactions have been reported in patients receiving atracurium in combination with one or more anesthetics.

Side effects with unknown frequency :

Convulsive seizures in patients in the Intensive Care Unit receiving atracurium in combination with other agents and usually presenting medical predispositions (e.g., head trauma, cerebral pathology or uremia).

-Myopathy, muscle weakness after a prolonged infusion of muscle relaxants in patients hospitalized in the Intensive Care Unit.

Reporting side effects

If you get any side effects, talk to your doctor or pharmacist. This also applies to any side effect not mentioned in this leaflet. You can also report side effects directly via the national reporting system.

5. HOW TO STORE ATRACURIUM MEDIS solution for injection in vial

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 box. The expiry date refers to the last day of the month.

This medication should be stored at a temperature ranging from 2 ° C to 8 ° C (in the refrigerator) and protected from light.

Do not freeze.

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

6. CONTENT OF THE PACKAGING AND OTHER INFORMATION

What ATRACURIUM MEDIS solution for injection in vial contains ?

•The active substance is :

	ATRACURIUM MEDIS 25 mg/2,5ml	ATRACURIUM MEDIS 50 mg/5 ml
Atracurium besilate	25 mg for a 2.5 ml vial.	50 mg for a 5 ml vial.

•The other components are :

20 percent benzene sulfonic acid solution, water for injection.

What ATRACURIUM MEDIS solution for injection in vial looks like and content of the outer packaging :

ATRACURIUM MEDIS 25 mg/2,5ml, solution for injection : Box of 50 or 10 vials of 2.5 ml.

ATRACURIUM MEDIS 50 mg/5 ml, solution for injection : Box of 50 or 10 vials of 5 ml.

Supply conditions : List I.

Marketing authorization number :

ATRACURIUM MEDIS 25 mg/2,5ml Solution for injection : Box of 50 vials of 2,5 ml : 923340 1H

ATRACURIUM MEDIS 25 mg/2,5ml solution for injection : Box of 10 vials of 2,5 ml : 923340 3H

ATRACURIUM MEDIS 50 mg/5 ml solution for injection : Box of 50 vials of 5 ml : 923340 2H

ATRACURIUM MEDIS 50 mg/5 ml solution for injection : Box of 10 vials of 5 ml : 923340 4H

Marketing authorization holder and manufacturer :

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This is a medicine

- A medicine is a product but not like any other product.
- A medicine is a product that affects your health if it's not used properly : it can be health threatening.
- Strictly adhere to the prescription of you Doctor and the use instructions prescribed, follow your pharmacist advice.
- Your doctor and you pharmacist know the medicine, its use and side effect.
- Don't stop the use of the treatment on your own during the prescribed time.
- Don't retake. Don't increase the doses without doctor's advice.

Keep the medicines out of reach of children

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V03

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UNITE PAO

B . A . T

Client : MEDIS
Contact: Walid KHALFALLAH
Désignation : ATRACURIUM MEDIS 25mg,50mg
Format : 15 x 23 cm
Impression : 1 couleur recto verso
logiciel : Indesign CS4, Illustrator CS4,
Opérateur : MARWA KARRA
Grammage de papier : 60g

Date : 14-05-2020
Code article : NO0046
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Police : times
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Interligne : 6,4
PREPLIEE AVEC BANDE

Signature client