PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER ATRACURIUM INJECTION

Atracurium Besylate 10mg/ml

Read this leaflet carefully before you start taking this medicine.

- If you have any further questions, ask your health care provider.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please inform your health care provider.

In this leaflet:

- 1. What Atracurium Injection is and what it is used for
- 2. What you need to know before you use Atracurium Injection
- 3. How to use Atracurium Injection
- 4. Possible side effects
- 5. How to store Atracurium Injection
- 6. Contents of the pack and other information

1. WHAT ATRACURIUM INJECTION IS AND WHAT IT IS USED FOR

Atracurium Injection contains a medicine called Atracurium Besylate. This belongs to a group of medicines called muscle relaxants.

Atracurium Injection is used:

- To relax muscles during surgical operations in 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.

Ask your doctor if you would like more explanation about this medicine.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE ATRACURIUM INJECTION

- Do not take Atracurium Injection if:
- You are allergic to Atracurium Besylate, any other muscle relaxant or any of the other ingredients in this medicine.
- You have reacted badly to an anaesthetic before

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

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking this medicine if:

- 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 severe electrolyte imbalance.

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER ATRACURIUM INJECTION

Atracurium Besylate 10mg/ml

- You have a lower-than-normal volume of blood (hypovolaemia)
- You have a burn which requires medical treatment.
- You have 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.

If you are not sure if any of the above applies to you, talk to your doctor, nurse or pharmacist before you are given this medicine.

Other medicines and Atracurium Injection

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

Tell your doctor, nurse or pharmacist if you are taking any of the following:

- Anaesthetics
- Antibiotics
- Medicines for heart conditions
- Medicines for high blood pressure
- 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 or pharmacist for advice before taking this medicine.

Driving and using machines

It can be dangerous to drive or operate machinery too soon after having had an operation. Your doctor will tell you how long to wait before you can drive and use machinery.

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER ATRACURIUM INJECTION

Atracurium Besylate 10mg/ml

3. HOW TO TAKE ATRACURIUM INJECTION

How your injection is given

You will never be expected to give yourself this medicine. It will always be given to you by a person who is qualified to do so.

This medicine 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.

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 take this medicine.

If you receive more Atracurium Injection than you should

This medicine 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, this medicine can cause side effects, although not everybody gets them. These effects are normally mild or moderate and often disappear after a short time.

Allergic reactions including anaphylactic shock

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

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

- Decrease in blood pressure.
- Reddening of your skin

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

Wheezing or coughing

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

• A lumpy skin rash or 'hives' anywhere on your body

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER ATRACURIUM INJECTION

Atracurium Besylate 10mg/ml

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

- Sudden wheeziness, chest pain or chest tightness
- Swelling of your eyelids, face, lips, mouth or tongue
- Decrease in heart rate
- Shock, circulatory failure, cardiac arrest

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 disease (myopathy) or muscle weakness

Reporting of side effects

If you get any side effect, talk to your doctor, pharmacist or nurse. This includes any possible side effect not listed in this leaflet.

By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE ATRACURIUM INJECTION

- Keep this medicine out of the sight and reach of children.
- Store between 2 and 8°C
- Do not use Atracurium Injection after the expiry date which is stated on the carton and label after 'EXP'. The expiry date refers to the last day of that month.

FURTHER INFORMATION. 6.

What ATRACURIUM INJECTION contains

Each ml of Atracurium Injection contains 10mg of Atracurium Besylate.

What ATRACURIUM INJECTION looks like and contents of the pack

Clear transparent liquid in 10x5ml glass ampoules packed in an inner carton

SUPPLIER AND MANUFACTURER

Fidson Healthcare Plc, 17-21, Fidson Avenue Sango-Ota, Ogun State, Nigeria. 234-(0)8077008888 Customercare@fidson.com

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER ATRACURIUM INJECTION Atracurium Paculata 10mg/ml

Atracurium Besylate 10mg/ml

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