

## 1.3.2 PATIENT INFORMATION LEAFLET

### SCHEDULING STATUS:

S4

### PROPRIETARY NAME, STRENGTH AND DOSAGE FORM:

TRACRIUM® Injection 2,5 ml (solution for injection)

TRACRIUM® Injection 5 ml (solution for injection)

Atracurium besylate 10 mg/ml

### Read all of this leaflet carefully before you are given TRACRIUM.

- Keep this leaflet. You may need to read it again.
- If you have any further questions about your illness, please ask your doctor, nurse or pharmacist.

### WHAT TRACRIUM CONTAINS:

The active ingredient is atracurium besylate.

Each 2,5 ml ampoule contains 25 mg atracurium besylate.

Each 5,0 ml ampoule contains 50 mg atracurium besylate.

Excipients: benzene sulphonic acid and water for injections.

### WHAT TRACRIUM IS USED FOR:

TRACRIUM belongs to a group of medicines called muscle relaxants.

TRACRIUM 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.

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

### **BEFORE YOU ARE GIVEN TRACRIUM:**

#### **You should not be given TRACRIUM:**

- if you are allergic to atracurium besylate, any other muscle relaxant or any of the other ingredients in TRACRIUM. The ingredients are listed at the beginning of this leaflet.
- if you have reacted badly to an anaesthetic before.

Do not use TRACRIUM if any of the above applies to you. If you are not sure, talk to your doctor or nurse before you are given TRACRIUM.

#### **Special care should be taken with TRACRIUM:**

Check with your doctor, nurse or pharmacist before having this medicine:

- if 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 have ever had an allergic reaction to any muscle relaxant which was given as part of an operation
- if you have muscle weakness, tiredness or difficulty in co-ordinating your movements (myasthenia gravis)
- if you have a neuromuscular disease, such as a muscle wasting disease, paralysis, motor neuron disease or cerebral palsy
- if you have severe electrolyte imbalance
- if you have a lower than normal volume of blood (hypovolaemia)
- if you have a burn which requires medical treatment.

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

**Pregnancy and breastfeeding:**

If you are pregnant or breast feeding your baby, please consult your doctor or other healthcare professional for advice before you are given TRACRIUM.

**Driving and using machinery:**

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

**Taking other medicines with TRACRIUM:**

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

In particular, tell your doctor if you are taking any of the following:

- anaesthetics, used to reduce sensation and pain during surgical procedures e.g. halothane, isoflurane, enflurane and ketamine
- antibiotics used to treat infections e.g. aminoglycosides, polymyxins, tetracyclines, lincomycin and clindamycin
- medicines for heart conditions e.g. propranolol, calcium channel blockers, lignocaine, procainamide, quinidine and ganglion blocking agents
- water tablets (diuretics) e.g. furosemide
- medicines containing magnesium sulphate e.g. medicines used to treat indigestion or heartburn
- medicines for mental illness e.g. lithium
- medicines used to treat epileptic fits (seizures) e.g. phenytoin and carbamazepine
- other medicines that work the same as TRACRIUM
- medicines used to treat Alzheimer's disease (e.g. anticholinesterases like donepezil).

**HOW TO RECEIVE TRACRIUM:**

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.

TRACRIUM 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.

You doctor will decide how 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 be given TRACRIUM.

**If you are given more TRACRIUM than you should:**

Since the healthcare professional will administer TRACRIUM, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

**POSSIBLE SIDE EFFECTS:**

TRACRIUM can have side effects.

Not all side effects reported for TRACRIUM are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using this medicine, please consult your doctor or other healthcare professional for advice.

**Allergic reactions:**

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

- decrease in blood pressure
- reddening of your skin

- wheezing or coughing
- a lumpy skin rash or 'hives' anywhere on your body
- 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.

A severe allergic reaction can occur when given one or more anaesthetic agents.

**Other side effects that may occur include:**

- fits (seizures)
- muscle weakness or muscle disease.

If you notice any side effects not mentioned on this leaflet, please inform your doctor.

**STORING AND DISPOSING OF TRACRIUM:**

Store all medicines out of reach of children.

Store between 2 °C and 8 °C. Do not freeze.

Protect from light.

Open ampoules of TRACRIUM should be discarded immediately after use.

**PRESENTATION OF TRACRIUM:**

Box of 5 x Ampoules of 2,5 ml.

Box of 5 x Ampoules of 5,0 ml.

**IDENTIFICATION OF TRACRIUM:**

2,5 ml and 5,0 ml ampoules containing a clear faint yellow solution for intravenous administration.

**REGISTRATION NUMBER:**

TRACRIUM Injection 2,5 ml: R/17.1/209

TRACRIUM Injection 5,0 ml: R/17.1/210

**NAME AND ADDRESS OF REGISTRATION HOLDER:**

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

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