TRACRIUM® for Injection

atracurium besilate

Consumer Medicine Information

What is in this leaflet?

This leaflet answers some common questions about Tracrium. It does not contain all of the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you being given Tracrium against the benefits this medicine is expected to have for you.

If you have any concerns about being given this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Tracrium is used for

Tracrium will be given to you or your child during surgery. It is used together with anaesthetic medicines to relax the body's muscles

Tracrium belongs to a group of medicines called "neuromuscular blockers".

Tracrium works by blocking the effects of one of the body's chemical messengers called acetylcholine. Acetylcholine is involved in muscle contraction.

Your doctor may have prescribed Tracrium for another reason.

Ask your doctor if you have any questions about why Tracrium has been prescribed for you.

There is no evidence that Tracrium is addictive.

Before you are given Tracrium

When you must not receive Tracrium

You must not receive
 Tracrium if you have ever had
 an allergic reaction to
 atracurium besilate or any of
 the ingredients listed at the
 end of this leaflet.

Symptoms of an allergic reaction may be mild or severe. They usually include some or all of the following: wheezing, swelling of the lips/mouth, difficulty in breathing, hayfever, lumpy rash ("hives") or fainting.

Before you receive Tracrium

You must tell your doctor if:

- you have had any adverse reactions during an operation.
- you have had any type of allergic reaction to muscle relaxants, or to any medicines used during an operation.
- you are allergic to any other medicines or any other substance, such as foods, dyes or preservatives.
- if you or a relative have had previous difficulties with anaesthetics.
- you have or have ever had any of the following medical conditions:
 - asthma or any other breathing

disorders

- heart disease
- kidney, liver disease or disease of the nervous system e.g. myaesthenia gravis
- you are pregnant, intend to become pregnant, are breast feeding or plan to breast feed.

Your doctor will discuss the possible risks and benefits of being given Tracrium if you are pregnant or breast-feeding.

If you have not told your doctor about any of the above, tell them before you are given Tracrium.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines you buy without a prescription from a pharmacy, supermarket or health food shop.

Tracrium may be affected by other medicines such as:

- antibiotics
- · drugs for the heart
- · blood pressure tablets
- · magnesium
- lithium
- other muscle blockers (e.g. hexamethonium) and anaesthetics

How Tracrium is given

Tracrium can be given into a vein in two ways:

- as an injection, or
- as a slow infusion.

Tracrium will be administered by an anaesthetist or other doctor with special training. You will never be

expected to give yourself this medication.

The dosage will vary according to many factors such as your body weight and the type of operation you have.

While you are using Tracrium

Things to be careful of

If you are discharged early, following treatment with Tracrium or any other anaesthetic agents, do not drive or operate machinery.

Side-Effects

Check with your doctor as soon as possible if you have any problems after receiving Tracrium, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Like other medicines, Tracrium can cause some side-effects.

The most commonly reported sideeffects are:

- · skin flushing
- · lowering of blood pressure
- changes in heart rate either increased or decreased
- · tight breathing
- · allergic reactions
- skin rash
- seizures (in certain patients)
- · muscle weakness

Ask your doctor or pharmacist to answer any questions you may have.

This is not a complete list of all possible side-effects. Others may occur in some people and there may be some side-effects not yet known.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list. Ask your doctor or pharmacist if you don't understand anything in this list.

Do not be alarmed by this list of possible side-effects. You may not experience any of them.

Tracrium 2.5mL : AUST R 11008 Tracrium 5mL : AUST R 39289 ©2017 Aspen Global Incorporated. Version 2.0

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Product description

What Tracrium looks like

Tracrium is clear slightly yellow solution supplied in glass ampoules and is available in two sizes of 2.5 mL & 5 mL.

Ingredients

Tracrium contains the active ingredient atracurium (as besilate) at a concentration of 10mg/mL. Other ingredients are benzenesulfonic acid and sterile water.

Tracrium does not contain lactose.

Sponsor

Your Tracrium is supplied by: Aspen Pharmacare Australia Pty Ltd 34-36 Chandos StreetSt Leonards NSW 2065 Australia

Further Information

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition. You may also be able to find general information about your disease and its treatment from books, for example in public libraries.

Do not throw this leaflet away.

You may need to read it again.

This leaflet was prepared on 16 January 2003.

Most recent update on 3 April 2017.

The information provided applies only to: Tracrium® for Injection.