Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before you are given DBL^{TM} Atracurium Besylate Injection (Atracurium), even if you have had this medicine before.

This leaflet answers some common questions about DBLTMAtracurium Besylate Injection. It does not contain all 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 taking DBLTMAtracurium Besylate Injection against the benefits they expect it will have for you.

If you have any questions about $DBL^{\rm TM}$ Atracurium Besylate Injection, ask your doctor or pharmacist.

Keep this leaflet in a safe place.

You may need to read it again.

What is DBL™ Atracurium Besylate Injection used for

Atracurium (*at-tra-CURE-ee-um*) is a muscle relaxant medicine. It is usually used together with a general anaesthetic to assist the use of a mechanical ventilator.

It is used prior to surgery to provide muscle relaxation during surgery or to provide muscle relaxation for medically assisted breathing. It will be given to you or your child when you/they are asleep during surgery.

It works by blocking acetylcholine, one of the body's chemical messengers. Acetylcholine is involved in muscle contraction.

However, your doctor may have prescribed Atracurium Besylate Injection for another purpose.

Ask your doctor if you have any questions about why it has been prescribed for you. This medicine is not addictive.

Before you are given DBL[™] Atracurium Besylate Injection

When you must not be given it You should not be given DBLTM Atracurium Besylate Injection if you are allergic to

- · medicines containing atracurium besilate
- medicines containing benzenesulfonic acid
- other muscle relaxant medicines.

If you have an allergic reaction you may have breathing difficulties, a skin rash, and swelling of the lips or tongue.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you are given it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

You must tell your doctor if you have or have had any of the following medical conditions:

 you have had any prior difficulties with anaesthetics

- you have any health problems, especially:
 - allergies
 - breathing problems (eg asthma)
 - heart, kidney or liver problems
 - myasthenia gravis or other nerve diseases.

Tell your doctor or pharmacist if you are pregnant or plan to become pregnant or are breast-feeding.

Your doctor can discuss with you the possible risks and benefits involved with being given DBL™ Atracurium Besylate Injection.

Taking other medicines

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

Some medicines and Atracurium may interfere with each other. These include:

- · antibiotics
- heart medicines (eg beta blockers such as propranolol or calcium channel blockers such as verapamil)
- Medicines used to treat arrhythmia (eg lignocaine or procainamide)
- fluid (water) medicines (eg frusemide, thiazides)
- · blood pressure medicines
- · magnesium sulfate
- medicines used to treat depression or psychosis (eg lithium or chlorpromazine)
- medicines used to treat malaria (eg quinine or chloroquine)
- corticosteroids (eg prednisolone)
- medicines used to treat epilepsy (eg carbamazepine or phenytoin

These medicines may be affected by atracurium or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

If you have not told your doctor about any of these things, tell him/her before you are given DBLTM Atracurium Besylate Injection.

How DBL™ Atracurium Besylate Injection is given

DBLTM Atracurium Besylate Injection should only be used under the supervision of your doctor

It is usually given as an intravenous injection or an infusion (ie a slow injection through a 'drip' into the vein).

If you receive too much (overdose)

As DBLTM Atracurium Besylate Injection is most likely to be given to you in hospital under the supervision of your doctor, it is very unlikely that you will receive an overdose.

However, if you were to receive an overdose of atracurium, immediate action would be taken to support your breathing and blood pressure. Other medicines can also be given to reverse the effects of atracurium.

In case of overdose, immediately contact the Poisons Information Centre for advice (In Australia, call 13 11 26. In New Zealand, call 0800 764 766).

While you are being given DBL™ Atracurium Besylate Injection

Things to be careful of

Allergic reactions

Some people may have an allergic reaction after receiving DBLTM Atracurium Besylate Injection.

If you notice any shortness of breath, change in heart rate or dizziness, tell your doctor immediately.

Be careful driving or operating machinery until you know how Atracurium affects you.

If you feel light-headed, dizzy or weak when getting out of bed or standing up, get up slowly.

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

Things you must not do

Do not take any other medicines, whether they are prescription or over-the-counter medicines, unless they have been approved or recommended by a doctor or pharmacist that knows you have been given DBLTM Atracurium Besylate Injection.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well after receiving DBLTM Atracurium Besylate Injection, even if you think the problem is not related to the medicine.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

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

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- skin rash
- · flushing of the skin
- wheezing
- irritation at injection site
- hives

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- · severe allergic reactions
- swelling of the face, lips or tongue
- · muscle weakness
- changes in blood pressure

- · changes in heart rate
- shortness of breath.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After you are given DBL™ Atracurium Besylate Injection

Storage

DBL™ Atracurium Besylate Injection will be stored in the pharmacy or on the ward. The injection is kept in the refrigerator where the temperature stays between 2 and 8°C. It should be protected from light.

Product description

What it looks like

DBLTM Atracurium Besylate Injection is a clear, colourless or faint yellow solution and comes in a glass ampoule.

Ingredients

Active ingredients:

DBL[™] Atracurium Besylate Injection contains atracurium besilate as the active ingredient.

Other ingredients:

- · Benzenesulfonic acid
- · Water for Injections

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes

Sponsor

 DBL^{TM} Attracurium Besylate Injection is supplied by:

Australian Sponsor:

Pfizer Australia Pty Ltd Sydney NSW

Toll Free Number: 1800 675 229

www.pfizer.com.au

DBLTM Atracurium Besylate Injection is available in two strengths:

- 25 mg/2.5 mL AUST R 57992
- 50 mg/5 mL AUST R 57993

This leaflet was updated in June 2019.