

DBL™ Rocuronium Bromide Injection

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am being treated with DBL Rocuronium Bromide?

DBL Rocuronium Bromide contains the active ingredient rocuronium bromide. Rocuronium is a muscle relaxant that is used when you/your child have an operation. It may also be used to relax the muscles in your windpipe making it easier to insert a tube to help you breathe during surgery or in the intensive care unit (ICU).

For more information, see Section [1. Why am I being treated with DBL Rocuronium Bromide?](#) in the full CMI.

2. What should I know before treatment with DBL Rocuronium Bromide?

Do not use if you/your child have ever had an allergic reaction to rocuronium or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you/your child have any other medical conditions, take any other medicines, are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before treatment with DBL Rocuronium Bromide?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with DBL Rocuronium Bromide and affect how it works. Examples include medicines used to: make you sleep during surgery; numb your body during a medical procedure; treat severe allergies and inflammation; treat infections; treat depression or bipolar disorder; treat heart disease or high blood pressure, treat fluid retention; treat malaria; treat pregnant women experiencing high blood pressure or toxins in the urine; treat epilepsy.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How will DBL Rocuronium Bromide be given to me?

DBL Rocuronium Bromide will be given to you by a doctor, by injection into a vein.

More instructions can be found in Section [4. How do I use DBL Rocuronium Bromide?](#) in the full CMI.

5. What should I know while using DBL Rocuronium Bromide?

Things you should do	<p>Before you/your child's operation, discuss your/your child's medical history with your doctor.</p> <p>Tell your doctor if you/your child are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.</p>
Driving or using machines	<p>Your doctor will tell you when it is safe to drive and operate potentially dangerous machinery after you have been given DBL Rocuronium Bromide</p>
Drinking alcohol	<p>No information available.</p>
Looking after your medicine	<p>DBL Rocuronium Bromide is stored in the hospital.</p>

For more information, see Section [5. What should I know while treatment with DBL Rocuronium Bromide?](#) in the full CMI.

6. Are there any side effects?

Side effects include sudden life-threatening allergic reactions (shortness of breath, wheezing, coughing or difficulty breathing, swelling of the face, lips, or tongue which may cause difficulty swallowing, swelling in other parts of the body; feeling lightheaded or dizzy, skin rash, itching, hives;) rapid, shallow breathing, cold, clammy skin, a rapid, weak pulse, feeling weak and fainting; sudden fever, rapid or irregular heartbeat, chest pain, rapid breathing, stiffness, pain and/or weakness in your muscles; loss of movement; dilated/enlarged pupils or fixed pupils; pain or irritation at the injection site; flushing.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

DBL™ Rocuronium Bromide Injection

Active ingredient(s): *Rocuronium* (Rok-you-RO-nee-um)

Consumer Medicine Information (CMI)

This leaflet provides important information about using DBL™ Rocuronium Bromide. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using DBL Rocuronium Bromide.**

Where to find information in this leaflet:

- [1. Why am I being given DBL Rocuronium Bromide?](#)
- [2. What should I know before treatment with DBL Rocuronium Bromide?](#)
- [3. What if I am taking other medicines?](#)
- [4. How will DBL Rocuronium Bromide be given to me?](#)
- [5. What should I know while being treated with DBL™ Rocuronium Bromide?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I being given DBL Rocuronium Bromide?

DBL Rocuronium Bromide contains the active ingredient rocuronium bromide.

Rocuronium is a muscle relaxant that is used when you/your child have an operation. It may also be used to relax the muscles in your windpipe making it easier to insert a tube to help you breathe during surgery or in the intensive care unit (ICU).

DBL™ Rocuronium Bromide is not addictive.

2. What should I know before treatment with DBL Rocuronium Bromide?

Warnings

DBL Rocuronium Bromide should not be used if you are allergic to rocuronium bromide, or any of the ingredients listed at the end of this leaflet.

Check with your doctor if you/your child:

- have kidney, liver or gall bladder disease
- have heart disease
- have swollen hands, ankles or feet

- have disease affecting the nerves and muscles (e.g., polio, myasthenia gravis, Eaton-Lambert Syndrome)
- have ever developed complications during anaesthesia, e.g., uncontrolled shivering due to a drop in body temperature or sudden fever with rapid heartbeat, rapid breathing and stiffness, pain and/or weakness in your muscles
- general ill-health (e.g., sudden, unexplained weight loss, fatigue, weakness)
- blood tests have shown any of the following medical conditions:
 - low potassium, calcium or protein levels in the blood
 - high magnesium levels in the blood
 - too much acid or carbon dioxide in the blood

If you are suffering from any of these conditions your doctor will take this into account when deciding the correct dose of rocuronium for you.

Tell your doctor if you:

- have allergies to any other medicines, foods, preservatives or dyes.
- take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Your doctor will discuss the risks and benefits of using rocuronium if you are pregnant or breast-feeding.

Children/Elderly

DBL Rocuronium Bromide can be used in infants (28 days-23 months), children (2-11 years), adolescents (12-18 years) and elderly patients .

DBL Rocuronium Bromide used in elderly patients (65 years and older) may be at an increased risk of residual paralysis.

3. What if I am taking other medicines?

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

Some medicines may interfere with DBL Rocuronium Bromide and affect how it works. These include:

- corticosteroids, medicines used to treat severe allergies or inflammation in various parts of your body
- some antibiotics
- lithium salts, a medicine used to treat and prevent mood swings (mania or depression) in manic-depression/bipolar disorder

- quinidine, calcium channel blockers, beta-blockers, medicines used to treat heart disease or high blood pressure
- diuretics (fluid tablets)
- quinine, a medicine used to treat malaria
- lignocaine and bupivacaine, medicines to numb the part of your body for a medical procedure.
- other muscle relaxants
- carbamazepine and phenytoin, medicines used to treat epilepsy
- magnesium salts, medicines used to treat constipation or in pregnant women experiencing high blood pressure.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect DBL Rocuronium Bromide.

4. How will DBL Rocuronium Bromide be given to me?

How much will be given

Your doctor will decide what dose of DBL Rocuronium Bromide you need and it will be injected into a vein.

When DBL Rocuronium Bromide will be given

DBL Rocuronium Bromide will be given to you by a doctor, by injection into a vein.

If you use too much DBL Rocuronium Bromide

As DBL Rocuronium Bromide Injection doses are carefully worked out and are given by a doctor experienced in its use, it is extremely unlikely that you will be given too much.

5. What should I know while using DBL Rocuronium Bromide?

Things you should do

If you are going to have an operation it is important that you discuss you/your child's medical history with your doctor as it can affect how this medicine affects you.

Things you should not do

Driving or using machines

Do not drive or use any machines or tools whilst under the effects of DBL Rocuronium Bromide .

Your doctor will tell you when it is safe to drive and operate potentially dangerous machinery after you have been given DBL Rocuronium Bromide.

Drinking alcohol

No information available.

Looking after your medicine

DBL Rocuronium Bromide is stored in a hospital which is responsible for storing and disposing of any unused product correctly.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Side effects

Side effects	What to do
<ul style="list-style-type: none">• pain or irritation at injection site• flushing• red skin rash or itchy rash	Speak to your doctor if you have any of these less serious side effects and they worry you.

Side effects

Side effects	What to do
<ul style="list-style-type: none">● Shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body; feeling lightheaded or dizzy; skin rash, itching, hives● rapid, shallow breathing, cold, clammy skin, a rapid, weak pulse, dizziness, weakness and fainting● sudden fever with rapid heartbeat, rapid breathing and stiffness, pain and/or weakness in your muscles● muscle weakness or paralysis● aching muscles or weakness, not caused by exercise Loss of movement● fast heartbeat	<p>If any side effects occur, they will mainly be while you are under anaesthesia and will be managed appropriately by your anaesthetist. Otherwise, tell your doctor or nurse straight away if you experience anything that worries you</p>

Side effects	What to do
<ul style="list-style-type: none"> ● chest pain, shortness of breath, nausea, vomiting and light-headedness ● dilated/enlarged pupils or fixed pupils 	

During and after your/your child's surgery, your doctor will monitor you/your child's response to DBL Rocuronium Bromide as well your recovery from anaesthesia and the effect of muscle relaxation.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What DBL Rocuronium Bromide contains

Active ingredient (main ingredient)	10 mg/mL of rocuronium bromide
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• sodium acetate• sodium chloride• acetic acid• sodium hydroxide• water for injections

Do not take this medicine if you are allergic to any of these ingredients.

This medicine does not contain preservatives.

It does not contain lactose, sucrose, gluten, tartrazine or any azo dyes.

What DBL Rocuronium Bromide looks like

DBL Rocuronium Bromide Injection is a clear, colourless to faintly yellow solution.

Australian Registration Number: AUST R 161275.

Who distributes DBL Rocuronium Bromide

Australian Sponsor

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free number: 1800 675 229 or
pfizermedicalinformation@pfizer.com.au

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