

DBL™ Rocuronium Bromide Injection

Rocuronium (Rok-you-RO-nee-um)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about DBL™ Rocuronium Bromide Injection (rocuronium).

It does not contain all the available information.

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

All medicines have risks and benefits. Your doctor has weighed the risks of you having DBL™ Rocuronium Bromide Injection against the benefits they expect it will have for you.

If you have any concerns about receiving this medicine, ask your doctor.

Keep this leaflet. You may need to read it again.

What DBL™ Rocuronium Bromide Injection is used for

Rocuronium is one of a group of medicines called muscle relaxants.

Muscle relaxants are used during an operation as part of the general anaesthetic.

When you have an operation, your muscles must be completely relaxed. This makes it easier for the surgeon to perform the operation.

Normally the nerves send messages to the muscles by impulses.

Rocuronium acts by blocking these impulses so the muscles are relaxed.

Because the muscles needed for breathing also become relaxed you will need help with your breathing (artificial respiration) during and after your operation until you can breath on your own.

During the operation the effect of the muscle relaxant is constantly checked and if necessary some more drug is given.

At the end of the operation the effects of the medicine are allowed to wear off and you can start breathing on your own. Sometimes another drug is given to help speed this up.

Rocuronium can also be used in intensive care to keep your muscles relaxed.

Ask your doctor if you want any more information about this medicine.

DBL™ Rocuronium Bromide Injection is not addictive.

Before you are given DBL™ Rocuronium Bromide Injection

When you must not be given it

You must not be given DBL™ Rocuronium Bromide Injection if you have an allergy to:

- any medicine containing rocuronium bromide
- any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include:

- shortness of breath,
- wheezing or difficulty breathing;
- swelling of the face, lips, tongue or other parts of the body;
- rash, itching or hives on the skin.

DBL™ Rocuronium Bromide Injection should not be given to a child under the age of one month.

The safety of administration of rocuronium has not been established in children under the age of one month.

Before you are given it

If you are going to have an operation it is important that you discuss the following points with your doctor, since it can influence the way this medicine is given to you.

Tell your doctor if you have or have had any medical conditions, especially the following:

- an allergy to muscle relaxants
- kidney disease
- liver or gallbladder disease
- heart disease
- polio, myasthenia gravis, Eaton-Lambert Syndrome or other diseases affecting nerves or muscles
- oedema (local or generalised swelling due to fluid)

Certain medical conditions may affect how DBL™ Rocuronium Bromide Injection works. These include:

- low potassium levels in the blood
- high magnesium levels in the blood
- low calcium levels in the blood
- low levels of protein in the blood
- dehydration
- too much acid in the blood
- too much carbon dioxide in the blood
- general ill-health (unexplained weight loss, fatigue, weakness)
- being overweight
- burns

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.

DBL™ Rocuronium Bromide Injection can be used in children (1 month old to adolescence) and the elderly but your doctor should first assess your medical history.

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

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

Your doctor will discuss the risks and benefits of using rocuronium 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 this medicine.

Taking other medicines

Tell your doctor 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 may be affected by rocuronium, or affect how well it works. These include:

- anaesthetics, medicines to make you sleep during surgery
- corticosteroids (anti-inflammatory medicines)

- antibiotics
- lithium, a medicine used to treat bipolar disorder
- medicines used to treat heart disease or high blood pressure (quinidine, calcium channel blockers, beta-blockers and diuretics (fluid tablets))
- quinine, a medicine used to treat malaria
- magnesium salts
- lignocaine and bupivacaine (local anaesthetics)
- other muscle relaxants
- carbamazepine and phenytoin, medicines used to treat epilepsy

You may need to use different amounts of your medicines or take different medicines. Your doctor will advise you.

Tell your doctor if you are taking magnesium sulphate to treat toxemia of pregnancy (preeclampsia).

The dose of rocuronium may need to be reduced.

Your doctor will have a complete list of medicines that may cause problems when used with rocuronium.

How DBL™ Rocuronium Bromide Injection is given

DBL™ Rocuronium Bromide Injection will be given by a doctor.

It will not be given to you until you are asleep from the anaesthetic.

It will be injected into a vein before and/or during an operation.

It will be given as a single injection or continuous infusion.

The usual dose is 0.6 mg rocuronium per kg body weight and the effect lasts 30-40 minutes.

During the operation your doctor will check whether rocuronium is still working.

You may be given additional doses if they are needed.

If you take too much (overdose)

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 Rocuronium.

However, if this does happen, your doctor will make sure that you continue breathing artificially until you can breathe on your own again. Your doctor may speed-up your recovery by giving you a drug that reverses the effects of rocuronium.

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

After having DBL™ Rocuronium Bromide Injection

Things to be careful of

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

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

Children should be careful when riding bicycles or climbing trees.

Side effects

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

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 list of side effects. You may not experience any of them.

Ask your doctor to answer any questions you may have.

Tell your doctor if you notice the following and they worry you:

- flushing
- pain at injection site
- irritation at injection site
- red skin rash or itchy rash

Tell your doctor immediately if you notice any of the following:

- fast or irregular heart beat
- dizziness, light-headedness (low blood pressure)
- muscle weakness or paralysis
- aching muscles or weakness, not caused by exercise
- wheezing, coughing
- rapid, shallow breathing,
- cold, clammy skin,
- a rapid, weak pulse,
- dizziness, weakness and fainting
- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing
- sudden signs of allergy such as rash, itching, hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or difficulty breathing.

These are serious side effects. You may need urgent medical attention or hospitalisation.

Storage

DBL™ Rocuronium Bromide Injection is stored in the hospital.

It should be kept in the refrigerator at 2-8 degrees Celsius and not be frozen.

DBL™ Rocuronium Bromide Injection can be stored outside the refrigerator at temperatures up to 30 degrees Celsius for a maximum of 12 weeks. Once it has been kept outside, it must not be placed back in the refrigerator.

Product description

What it looks like

DBL™ Rocuronium Bromide Injection comes in a vial containing a clear, colourless to faintly yellow solution.

Ingredients

Active ingredient

DBL™ Rocuronium Bromide Injection contains 10 mg/mL of rocuronium bromide as the active ingredient.

Inactive ingredients

It also contains:

- sodium acetate
- sodium chloride
- acetic acid
- sodium hydroxide
- water for injections

DBL™ Rocuronium Bromide Injection contains no preservative.

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

Sponsor

DBL™ Rocuronium Bromide Injection is supplied by:

Australian Sponsor

Pfizer Australia Pty Ltd
Sydney NSW
Toll Free number: 1800 675 229
www.pfizer.com.au

New Zealand Sponsor

Pfizer New Zealand Ltd
PO Box 3998
Auckland, New Zealand
Toll Free number: 0800 736 363

DBL™ Rocuronium Bromide Injection is available in the following strength:

- 50 mg/ 5 mL vials
AUST R 161275

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