Consumer Medicine Information

What is in this leaflet

This leaflet is a summary of some of the information about the drug Norcuron.

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 Norcuron against the benefits they expect it will have for you.

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

Keep this leaflet.

You may need to read it again.

What Norcuron is used for

Norcuron 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. Norcuron 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 breathe on your own. During the operation the effect of the muscle relaxants is constantly checked and if necessary some more drug is given. At the end of the operation the effects of Norcuron are allowed to wear off and you can start breathing on your own. Sometimes another drug is given to help speed this up. Norcuron can also be used in Intensive Care to keep your muscles relaxed.

Ask your doctor if you have any questions about this medicine.

Norcuron is not addictive.

Before you are given Norcuron

When you must not be given it You must not be given Norcuron if you have

an allergy to:

- any medicine containing vecuronium 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.

Norcuron should not be given to a child under the age of one month.

The safety of administration of Norcuron 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 Norcuron 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
- a heart disease
- diseases affecting nerves or muscles
- oedema (local or generalised swelling due to fluid)

Certain medical conditions may affect how Norcuron works:

- 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
- overweight
- burn

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

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

If you have not told your doctor about any of the above, tell him/her before you are given Norcuron.

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 Norcuron, or affect how well it works. These include:

- anaesthetics, medicines to make you sleep during surgery
- long term concurrent use of corticosteroids (anti-inflammatory medicines) and Norcuron in the Intensive Care Unit
- 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, medicine used to treat malaria
- magnesium salts
- lignocaine, a local anaesthetic
- other muscle relaxants
- phenytoin and carbamazepine, medicines used to treat epilepsy
- cimetidine, a medicine used to treat reflux and stomach ulcers

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

If you are taking magnesium sulphate to treat toxaemia of pregnancy (preeclampsia), tell your doctor as the dose of Norcuron may need to be reduced.

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

How Norcuron is given

Norcuron 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 0.1 mg vecuronium bromide per kg body weight and the effect lasts 20-40 minutes. During the operation your doctor will check whether Norcuron is still working. You may be given additional doses if they are needed.

Overdose

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

After having Norcuron

Things to be careful of

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

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 for 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 heart beat
- dizziness, light-headedness (low blood pressure)
- muscle weakness or paralysis
- aching muscles or weakness, not caused by exercise
- wheezing, coughing
- difficulty breathing

- 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 trouble breathing

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

Storage

Norcuron is stored in the hospital.

It must be kept below 25°C and protected from light.

Product description

What it looks like

A white powder, which is dissolved with sterile water for injection immediately before use.

Packs

- Norcuron 4 mg*: Ampoules in packs of 10 with or without solvent (water for injections).
- Norcuron 10 mg: Vials in packs of 10 without solvent.
- * Presentation not currently marketed in Australia.

Ingredients

Norcuron contains 4 mg or 10 mg of vecuronium bromide as the active ingredient. It also contains:

- · citric acid monohydrate
- · sodium phosphate dibasic dihydrate
- sodium hydroxide
- · phosphoric acid
- mannitol

No preservative has been added.

Sponsor

Merck Sharp & Dohme (Australia) Pty Limited

Level 1, Building A 26 Talavera Road Macquarie Park, NSW 2113 Australia

Australian Registration Numbers:

AUST R 18629 (with solvent) (4 mg) AUSTR 177718 (4 mg) AUST R 18636 (10 mg)

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This leaflet was updated in September 2014.