VECURE

Consumer Medicine Information (CMI) summary

The <u>full CMI</u> on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using VECURE?

VECURE contains the active ingredient vecuronium bromide. VECURE is used to relax your muscles during an operation as part of the general anaesthetic.

For more information, see Section <u>1. Why am I using</u> VECURE? in the full CMI.

2. What should I know before I use VECURE?

Do not use if you have ever had an allergic reaction to vecuronium bromide or any of the ingredients listed at the end of the CMI.

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

For more information, see Section 2. What should I know before I am given VECURE? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with VECURE and affect how it works.

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

4. How is VECURE given?

- VECURE 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 during the operation.

More instructions can be found in Section <u>4. How is</u> <u>VECURE given?</u> in the full CMI.

5. What should I know after I am given VECURE?

Driving or using machines

- Be careful before you drive or use any machines or tools until you know how VECURE affects you.
- Your doctor will tell you when it is safe to drive and operate potentially

	dangerous machinery after you have been given VECURE
Looking after your medicine	 VECURE is stored in the hospital. It must be kept below 25°C and protected from light.

For more information, see Section <u>5. What should I know after I am given VECURE?</u> in the full CMI.

6. Are there any side effects?

Less serious side effects: flushing, pain or irritation at injection site, red skin rash or itchy rash.

Serious side effects: 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.

For more information, including what to do if you have any side effects, see Section <u>6. Are there any side</u> <u>effects?</u> in the full CMI.

VECURE

Active ingredient: vecuronium bromide

Consumer Medicine Information (CMI)

This leaflet provides important information about using VECURE. 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 VECURE.

Where to find information in this leaflet:

- 1. Why am I using VECURE?
- 2. What should I know before I am given VECURE?
- 3. What if I am taking other medicines?
- 4. How is VECURE given?
- 5. What should I know after I am given VECURE?
- 6. Are there any side effects?
- 7. Product details

1. Why am I using VECURE?

VECURE contains the active ingredient vecuronium bromide. VECURE belongs to 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. VECURE 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 VECURE are allowed to wear off and you can start breathing on your own. Sometimes another drug is given to help speed this up. VECURE can also be used in Intensive Care to keep your muscles relaxed.

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

VECURE is not addictive.

2. What should I know before I am given VECURE?

Warnings

You must not be given VECURE if:

- you are allergic to vecuronium bromide, or 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.
 Always check the ingredients to make sure you can use this medicine.

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 VECURE is given to you.

Tell your doctor if you:

- have or have had any of the following medical conditions:
 - o an allergy to muscle relaxants
 - kidney disease
 - liver or gall bladder disease

- heart disease
- diseases affecting nerves or muscles
- oedema (local or generalised swelling due to fluid).

Certain medical conditions may affect how VECURE 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
- burns.

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

- have any allergies to any other medicines, food, 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 <u>6</u>. Are there any side effects?

Pregnancy and breastfeeding

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

Tell your doctor if you are breastfeeding or plan to breastfeed.

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

Use in infants

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

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

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

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 be affected by VECURE, or affect how well it works. These include:

 anaesthetics, medicines to help you sleep during surgery

- long term concurrent use of corticosteroids (antiinflammatory medicines) and VECURE 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
- lidocaine, 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 sulfate to treat toxaemia of pregnancy (preeclampsia), tell your doctor as the dose of VECURE may need to be reduced.

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

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

4. How is VECURE given?

VECURE 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 during the 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 VECURE is still working. You may be given additional doses if they are needed.

If you are given too much VECURE

As VECURE 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 medicine. 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 VECURE.

5. What should I know after I am given VECURE?

Driving or using machines

Be careful before you drive or use any machines or tools until you know how VECURE affects you.

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

Looking after your medicine

VECURE is stored in the hospital. It must be kept below 25°C and protected from light.

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.

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

Less serious side effects

Less serious side effects	What to do
 flushing pain at injection site irritation at injection site red skin rash or itchy rash 	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
 fast heart beat dizziness, light- headedness (low blood pressure) 	Call your doctor straight away if you notice any of these serious side effects.
 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 	You may need urgent medical attention or hospitalisation.

Serious side effects	What to do
 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 	

Tell your doctor, nurse 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 VECURE contains

Active ingredient (main ingredient)	vecuronium bromide
Other ingredients (inactive ingredients)	 citric acid dibasic sodium phosphate sodium hydroxide phosphoric acid mannitol
Potential allergens	gluten from maize and/or wheat

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

What VECURE looks like

The powder for injection is a white lyphoilised cake. This is dissolved with sterile water for injection immediately before use. (AUST R 165350).

VECURE comes in packs of 10 vials without solvent.

Who distributes VECURE

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

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