

## **Package leaflet: Information for the patient**

### **Vecuronium bromide 10 mg powder for solution for injection/infusion**

vecuronium bromide

**Read all of this leaflet carefully before you are given this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your anaesthetist or other doctor.
- If you get any side effects, talk to your anaesthetist or doctor. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet**

1. What Vecuronium bromide is and what it is used for
2. What you need to know before Vecuronium bromide is given to you
3. How Vecuronium bromide is given
4. Possible side effects
5. How to store Vecuronium bromide
6. Contents of the pack and other information

#### **1. What Vecuronium bromide is and what it is used for**

Vecuronium bromide is one of a group of drugs called muscle relaxants.

Muscle relaxants are used during an operation as part of a general anaesthetic. When you have an operation your muscles must be completely relaxed. This makes it easier for the surgeon to perform the operation. Vecuronium bromide is used as a muscle relaxant in adults, in children and adolescents (2-17 years) and in new born babies and infants (0 days –23 months).

Normally, your nerves send messages called impulses to your muscles. Vecuronium bromide acts by blocking these impulses so that your muscles relax. Because your breathing muscles also relax, you will need help to breathe (artificial ventilation) during and after your operation until you can breathe on your own again.

During the operation your anaesthetist will keep a check on the effect of the muscle relaxant, and if necessary will give you some more. At the end of surgery, the effects of the drug are allowed to wear off and you will start breathing on your own. Sometimes the anaesthetist will give you another drug to help speed this up.

#### **2. What you need to know before Vecuronium bromide is given to you**

##### **You should not be given Vecuronium bromide**

- if you are allergic to vecuronium, the bromide ion or any of the other ingredients of this medicine (listed in section 6).

Tell your anaesthetist if this applies to you.

##### **Warnings and precautions**

Talk to your anaesthetist before you receive Vecuronium bromide.

- if you are allergic to muscle relaxants
- if you have had kidney, heart, liver or gall bladder disease
- if you have had diseases affecting nerves and muscles

- if you have fluid retention (oedema).

Tell your anaesthetist if any of these applies to you.

**Some conditions may influence the effects of Vecuronium bromide, for example:**

- low calcium levels in the blood
- low potassium levels in the blood
- high magnesium levels in the blood
- low levels of protein in the blood
- too much acid in the blood
- too much carbon dioxide in the blood
- loss of too much water from the body, for example by being sick, diarrhoea or sweating (dehydration)
- over-breathing leading to too little carbon dioxide in the blood (alkalosis)
- general ill-health
- burns
- being very overweight (obesity)
- very low body temperature (hypothermia).

If you have any of these conditions, your anaesthetist will take this into account when deciding the correct dose of Vecuronium bromide for you.

**Other medicines and Vecuronium bromide**

Tell your anaesthetist or doctor or pharmacist if you are taking, have recently taken, or might take, any other medicines. Vecuronium bromide may affect other medicines or be affected by them.

**Medicines which increase the effect of Vecuronium bromide:**

- certain antibiotics
- certain medicines for heart disease or high blood pressure (water tablets, calcium channel blockers, beta-blockers and quinidine)
- certain anti-inflammatory medicines (corticosteroids)
- medicines for manic depressive illness (bipolar disorder)
- magnesium salts
- the medicine called cimetidine, used to treat stomach ulcers, heartburn or acid reflux
- local anaesthetics (lidocaine)
- medicines which cause increased volume of urine (diuretics).

**Medicines which decrease the effect of Vecuronium bromide:**

- chronic use of medicines for epilepsy (phenytoin, carbamazepine)
- calcium chloride and potassium chloride.

In addition, you may be given other medicines before or during surgery which can alter the effects of Vecuronium bromide. These include certain anaesthetics, other muscle relaxants, medicines such as phenytoin and medicines which reverse the effects of Vecuronium bromide. Vecuronium bromide may make certain anaesthetics work more quickly.

Your anaesthetist or doctor will take this into account when deciding the correct dose of Vecuronium bromide for you.

**Pregnancy and breast-feeding**

Tell your anaesthetist if you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby.

Your anaesthetist may still give you Vecuronium bromide, but you need to discuss it first. Vecuronium bromide may be given to you if you are having a Caesarean section.

**Driving and using machines**

Do not drive or use machines until advised it is safe to do so. Because Vecuronium bromide is given as part of a general anaesthetic, you may feel tired, weak or dizzy for some time afterwards. Your anaesthetist will be able to advise you on how long the effects are likely to last.

### **Vecuronium bromide contains sodium**

This medicine contains less than 1 mmol sodium (23 mg) per vial, that is to say essentially 'sodium-free'.

### **3. How Vecuronium bromide is given**

Vecuronium bromide will be given to you by your anaesthetist. Vecuronium bromide is given intravenously (into a vein), either as single injections or as a continuous infusion (a drip).

#### **The dose**

Vecuronium bromide can be used in adults and children of all ages including infants and newborns. Your anaesthetist will work out the dose of Vecuronium bromide you need based on:

- the type of anaesthetic
- the expected length of the operation
- other drugs you are taking
- your state of health
- your age.

The normal dose is 80 – 100 micrograms per kg body weight and the effect will last 24 - 60 minutes. During the procedure it will be checked whether Vecuronium bromide is still working. You may be given additional doses if they are needed.

#### **If you receive more Vecuronium bromide than you should**

As your anaesthetist will be monitoring your condition carefully it is unlikely that you will be given too much Vecuronium bromide. However if this happens, your anaesthetist will keep you breathing artificially (on a ventilator) until you can breathe on your own. It is possible to counteract the effects of (too much) Vecuronium bromide and speed-up your recovery by giving you a drug that reverses the effect of Vecuronium bromide. You will be kept asleep while this takes place.

If you have any further questions on the use of this medicine, ask your anaesthetist or other doctor.

### **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them. If these side effects occur while you are under anaesthetic, they will be seen and treated by your anaesthetist.

#### **Uncommon** (may affect up to 1 in 100 people)

- the medicine is too effective, or not effective enough
- the medicine works for longer than expected
- lowering of blood pressure
- increase in heart rate
- delayed recovery from anaesthesia.

#### **Very rare** (may affect up to 1 in 10,000 people)

- allergic (hypersensitivity) reactions (such as difficulty in breathing, collapse of the circulation or shock)
- muscle weakness or disorder
- paralysis
- wheezing of the chest

- swelling, rash or redness of the skin
- swelling of the face (face oedema)
- pain near the site of injection
- airway complication due to anaesthesia.

### **Reporting of side effects**

If you get any side effects, talk to your doctor or anaesthetist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Vecuronium bromide**

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and vial after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Do not use vecuronium bromide when the solution after reconstitution contains particles or is not clear.

Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **6. Contents of the pack and other information What Vecuronium bromide contains**

- The active substance is vecuronium bromide. Each vial contains 10 mg of vecuronium bromide.
- The other ingredients are citric acid anhydrous, disodium hydrogen orthophosphate anhydrous, mannitol (E421) and water for injections.

## **What Vecuronium bromide looks like and contents of the pack**

Vecuronium bromide is a white powder for solution for injection/infusion. There is 1 glass vial containing vecuronium bromide in each pack.

## **Marketing Authorisation Holder and Manufacturer**

### Marketing Authorisation Holder

Neon Healthcare Ltd  
8 The Chase, John Tate Road, Hertford, SG13 7NN, UK

### Manufacturer

DREHM Pharma GmbH  
Hietzinger Hauptstrasse 37/2, A-1130 Vienna, Austria

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**The following information is intended for healthcare professionals only:**

## **Preparation and handling**

### **Reconstitution**

Vecuronium bromide 10 mg powder for solution for injection/infusion

Addition of 5 ml water for injections results in an isotonic solution of pH 4 containing 2 mg vecuronium bromide per ml (2 mg/ml).

Alternatively, in order to obtain a solution with a lower concentration Vecuronium bromide may be reconstituted with a volume up to 10 ml of the following infusion fluids:

- 5% glucose injection fluid
- 0.9% sodium chloride injection fluid
- Lactated Ringer's solution
- Lactated Ringer's injection and 5% glucose
- Glucose 5% and 0.9% sodium chloride injection
- Water for injections.

Chemical and physical in-use (i.e. following reconstitution) stability has been demonstrated for 36 hours at 2-8°C and at 15-25°C.

From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8°C, unless reconstitution/dilution has taken place in controlled and validated aseptic conditions.

### **Compatibilities**

When Vecuronium bromide is reconstituted with water for injections, the resultant solution can be mixed with the following infusion fluids, packed in PVC or glass, to a dilution up to 40 mg/litre:

- 0.9% NaCl solution
- 5% glucose solution
- Ringer's solution
- Ringer's glucose
- Lactated Ringer's solution
- Lactated Ringer's solution and 5% glucose
- Glucose 5% and 0.9% sodium chloride solution
- Haemaccel
- Dextran-40 5% in 0.9% sodium chloride solution
- Water for injections.

Compatibility studies with other infusion fluids have not been performed.