B. PACKAGE LEAFLET

Package leaflet: Information for the user

Vecuronium 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 doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Vecuronium is and what it is used for

Vecuronium contains the active substance vecuronium bromide, which belongs to a group of medicines 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 is used as a muscle relaxant in adults, in children and adolescents (2-17 years) and in newborn babies and infants (0 days – 23 months).

Normally, your nerves send messages called impulses to your muscles. Vecuronium 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 doctor 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 doctor will give you another drug to help speed this up.

2. What you need to know before you are given Vecuronium

You must not be given Vecuronium
- if you are allergic to vecuronium, the bromide ion or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor, pharmacist or nurse before you are given Vecuronium
- if you are allergic to any muscle relaxants
- if you have reduced renal function or a renal disease
- if you have a heart disease or a disease affecting your blood circulation

- if you have an accumulation of fluid beneath the skin (for example swelling of the ankles)
- if you have a liver or a gallbladder disease
- if you have diseases affecting nerves and muscles (for example polio (poliomyelitis), myasthenia gravis, Eaton-Lambert syndrome).

Some conditions may influence the effects of Vecuronium, for example
- low potassium levels in the blood (hypokalaemia; caused for example by severe vomiting or by severe diarrhoea)
- high magnesium levels in the blood (hypermagnesaemia)
- low calcium levels in the blood (hypocalcaemia; caused by blood transfusion)
- low levels of proteins in the blood (hypoproteinaemia)
- loss of too much water from the body (dehydration; caused for example by being sick, diarrhoea or sweating)
- over-breathing (hyperventilation) leading to too little carbon dioxide in the blood (alkalosis)
- too much acid in the blood or body tissue (acidosis)
- an increased level of carbon dioxide in the blood (hypercapnia)
- general ill-health (cachexia)
- being very overweight (obesity)
- burns
- drop in body temperature (hypothermia) during anaesthesia.

If you have any of the conditions listed above, your doctor will take them into account when deciding the correct dose of Vecuronium for you.

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

Medicines which increase the effect of Vecuronium
- certain medicines used to make you sleep during surgery (anaesthetics; for example suxamethonium)
- certain medicines to treat bacterial infections (antibiotics; for example aminoglycosides, lincosamide and polypeptide antibiotics, acylamino-penicillin antibiotics)
- medicines which increase the amount of urine (diuretics or water tablets)
- medicines used for the treatment of heart disease or high blood pressure (calcium channel blockers, beta-blockers and quinidine)
- medicines used to treat mania, manic depressive illness or depression (lithium)
- certain medicines used to treat stomach ulcers, heartburn or acid reflux (cimetidine)
- some laxatives such as magnesium salts
- long-term concomitant use of certain anti-inflammatory medicines (corticosteroids)
- certain medicines for reducing pain (local anaesthetics; for example lidocaine)
- short-term concomitant use of certain medicines used for epilepsy (phenytoin).

Medicines which decrease the effect of Vecuronium
- certain medicines used for epilepsy (for example phenytoin or carbamazepine)
- calcium chloride and potassium chloride.

Medicines with variable effect
- other muscle relaxants.

Effect of Vecuronium on other drugs
- Vecuronium may make certain anaesthetics (for example lidocaine) work more quickly.

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

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor, pharmacist or nurse for advice before you are given this medicine.

Your doctor may still give you Vecuronium, but you need to discuss it first. Vecuronium 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 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.

3. How Vecuronium is used

Follow carefully all instructions given to you by your doctor or nurse. Check with your doctor or nurse if you are not sure.

How much and when Vecuronium is given
Vecuronium can be used in adults and children of all ages. The dose will be determined by the doctor. You will be given Vecuronium before or during a surgical procedure. The usual dose is 0.08 to 0.1 mg vecuronium bromide per kg body weight and the effect will last for 24 to 60 minutes. During the procedure it will be checked whether Vecuronium is still working.

You may be given additional doses if they are needed. The dose that you receive will depend on various factors. These include possible interactions with any other drugs you may have been given, the expected duration of the operation, your age and the state of your health.

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

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

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

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 doctor.

Uncommon/rare side effects (may affect up to 1 in 100 people)
- the drug is too effective, or not effective enough
- the drug works for longer than expected
- lowering of blood pressure (hypotension)
- increase in heart rate (tachycardia)
- delayed recovery from anaesthesia.

Very rare side effects (may affect up to 1 in 10,000 people)
- allergic (hypersensitivity) reactions (such as rash, itching, difficulty in breathing or swelling of the face, lips, throat or tongue)
- muscle weakness or paralysis
- failure of circulation (circulatory collapse and shock)
- excessive blushing
- tightness of the chest, associated with coughing, wheezing or breathlessness immediately after inhalation (bronchospasm)
- rapid swelling under the skin (angioneurotic oedema)
- skin rash, sometimes with intense itching and hives
- rash or redness of the skin (erythematous rash)
- swelling of the face (face oedema)
- pain near the site of injection
- airway complication of anaesthesia
- prolonged muscle disorder usually seen after the use of Vecuronium in combination with steroids (corticosteroids including an inflammatory effect) in severe ill patients (steroid myopathy).

Reporting of side effects
If you get any side effects, talk to your doctor , pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Vecuronium

Your doctor, pharmacist or nurse knows how to store Vecuronium properly.

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

This medicine must not be used 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.

Do not store above 25°C.

Chemical and physical in-use (i.e. following reconstitution) stability has been demonstrated for 24 hours at 15 to 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.

6. Contents of the pack and other information

What Vecuronium contains
- The active substance is vecuronium bromide. Each vial contains vecuronium as 10 mg vecuronium bromide.
- The other ingredients are citric acid anhydrous, disodium phosphate anhydrous, mannitol (E421), sodium hydroxide (for pH adjustment) and phosphoric acid concentrated (for pH adjustment).

What Vecuronium looks like and contents of the pack
Vecuronium is a white to off-white lyophilised powder, for solution for injection/infusion.

Vecuronium is supplied in packs containing 1, 4, 10 or 20 vials.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Sun Pharmaceutical Industries Europe B.V.
Polarisavenue 87
2132 JH Hoofddorp
The Netherlands

This medicinal product is authorised in the Member states of the EEA under the following names

Germany:	Vecuronium SUN 10 mg Pulver zur Herstellung einer Injektions/Infusionslösung
The Netherlands:	Vecuronium SUN 10 mg poeder voor oplossing voor injectie en intraveneuze infusie
United Kingdom	Vecuronium 10 mg powder for solution for injection/infusion

This leaflet was last revised in June 2019

The following information is intended for healthcare professionals only

How to prepare and administer Vecuronium

Vecuronium should be administered following reconstitution. Vecuronium is administered intravenously either as a bolus injection or as a continuous infusion.

Reconstitution
Addition of 5 ml water for injections results in a solution of pH 4 and osmolality of 200 mOsm/kg containing 2 mg vecuronium bromide per ml (2 mg/ml), each vial contains 10 mg vecuronium bromide which is equivalent to 8.75 mg of vecuronium.

Alternatively, in order to obtain a solution with a lower concentration Vecuronium 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.

Compatibilities
When Vecuronium 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.

The above-mentioned reconstituted solution can also be injected in to the line of a running infusion of the following fluids
- 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.