VECURE

Vecuronium 10 mg

alphapharm
A Mylan Company

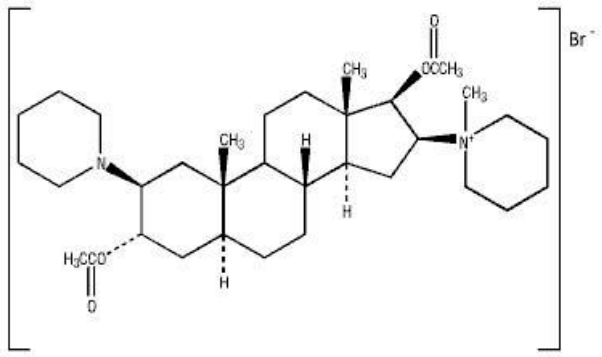
PRODUCT INFORMATION

NAME OF THE MEDICINE

Active ingredient : Vecuronium bromide

Chemical name : 1-[3alpha,17beta-diacetoxy-2beta- (piperidin-1-yl)-5alpha- androstan-16beta-yl]-1-methylpiperidinium bromide

Structural formula :



Vecuronium bromide

Molecular formula : $C_{34}H_{57}BrN_2O_4$ Molecular weight : 637.73

DESCRIPTION

Vecuronium bromide is a monoquaternary steroid derivative, homologous with pancuronium bromide. It is an odourless, bitter tasting, white to creamy white, microcrystalline powder. At 25° C (pH 3), its solubility is 16 mg/mL, and pKa is 8.97. Because vecuronium bromide hydrolyses rapidly in water, a ready for use aqueous solution form is not available.

Following reconstitution with solvent (water for injections), the resultant solution is isotonic and has a pH of 4.

Inactive ingredients: Anhydrous citric acid, dibasic anhydrous sodium phosphate, sodium hydroxide and/or phosphoric acid to buffer and adjust pH; and mannitol to make the reconstituted solution isotonic.

PHARMACOLOGY

Pharmacodynamics

VECURE is a nondepolarising neuromuscular blocking agent possessing all of the characteristic pharmacological actions of this class of drugs (curariform). It acts by competing for cholinergic receptors at the motor endplate. The antagonism to acetylcholine is inhibited and neuromuscular block is reversed by acetylcholinesterase inhibitors, e.g. neostigmine, edrophonium and pyridostigmine. The neuromuscular block can also be reversed by sugammadex, a Selective Relaxant Binding Agent. The potency of VECURE is equal to or somewhat greater than that of pancuronium; the duration of neuromuscular blockade produced by VECURE is significantly shorter than that of pancuronium at initially equipotent doses with less cumulative effect. The time to onset of paralysis decreases and the duration of maximum effect increases with increasing vecuronium doses. The use of an appropriate neuromuscular monitoring technique may be of benefit in assessing the degree of muscular relaxation.

An initial VECURE dose of 0.10 mg/kg generally produces first depression of twitch in approximately one minute, good or excellent intubation conditions within 2.5 to 3 minutes and maximum neuromuscular blockade within three to five minutes of injection in most patients. Because of the minimal tendency for cumulation,

frequent maintenance doses can be given in succession. VECURE is suitable for both short and prolonged operations.

At the clinical dosage vecuronium bromide has no vagolytic or ganglion blocking actions and histamine release is not expected to be clinically significant. Therefore, side effects on the cardiovascular and pulmonary systems are not to be expected. It does not counteract those haemodynamic changes or known side effects produced by or associated with anaesthetic agents and the likelihood of reflex bradycardia may thus be increased. It has no known effect on consciousness, the pain threshold or cerebration.

The action of vecuronium bromide can be antagonised either by sugammadex or by acetylcholinesterase inhibitors, e.g. neostigmine, pyridostigmine or edrophonium, in appropriate dosage. Sugammadex can be given for routine reversal at 1-2 post-tetanic counts to reappearance of T_2. Acetylcholinesterase inhibitors can be administered at reappearance of T_2 or at the first signs of clinical recovery.

Paediatric patients

Infants

The ED_{95} dose of vecuronium under nitrous oxide in oxygen anaesthesia was found to be approximately the same (approximately 47 microgram/kg bodyweight) as in adults. The onset of time is considerably shorter in infants as compared to children and adults, probably due to the shorter circulation time and relatively large cardiac output. Also, greater sensitivity of the neuromuscular junction to the action of neuromuscular blocking agents in these patients may account for a more rapid onset of action.

The duration of action and recovery time with vecuronium is longer in infants than in adults. Maintenance doses of VECURE should, therefore, be less frequently administered (see **PRECAUTIONS - Paediatric use** and **DOSAGE AND ADMINISTRATION**).

Children

The ED_{95} dose of vecuronium under nitrous oxide in oxygen anaesthesia was found to be higher than in adults (0.081 versus 0.043 mg/kg bodyweight, respectively). In comparison to adults, the duration of action and recovery time with vecuronium in children are in general approximately 30 and 20 to 30% shorter, respectively.

Similar to adults, cumulative effects with repeat maintenance doses of approximately one-quarter of the initial dose and administered at 25% recovery control twitch height are not observed in paediatric patients.

Pharmacokinetics

After intravenous administration of 0.1 to 0.15 mg/kg vecuronium, the distribution half-life of vecuronium amounts to 1.2 to 1.4 minutes. Vecuronium is mainly distributed in the extracellular fluid compartment. At steady state, the volume of distribution is 0.16 to 0.51 $L.kg^{-1}$ in adult patients.

The plasma clearance of vecuronium amounts to 3.0 to 5.6 $kg^{-1}.minute^{-1}$ and its plasma elimination half-life is 36 to 117 minutes.

The extent of metabolism of vecuronium is relatively low. In humans, a 3-hydroxy derivative having approximately 50% less neuromuscular blocking potency than vecuronium is formed in the liver. In patients not suffering from renal or hepatic failure, the plasma concentration of this derivative is low and does not contribute to the neuromuscular block occurring after administration of VECURE.

Biliary excretion is the main elimination route. It is estimated that within 24 hours after intravenous administration of VECURE, 40 to 60% of the dose administered is excreted into the bile as monoquaternary compounds. Approximately 95% of these monoquaternary compounds is unchanged vecuronium and less than 5% is 3-hydroxy vecuronium. Prolonged duration of action has been observed in patients with liver disease and/or biliary tract disease, probably as a result of decreased clearance leading to an increased elimination half-life.

Renal elimination is relatively low. The amount of monoquaternary compounds excreted in the urine collected by intravesical catheter for 24 hours following vecuronium administration is 20 to 30% of the dose administered.

In patients with renal failure, the duration of action may be prolonged. This is probably the result of a reduced plasma clearance.

INDICATIONS

Skeletal muscle relaxant for use as an adjunct to general anaesthesia in adults and children for all surgical procedures.

CONTRAINDICATIONS

Known hypersensitivity to any components of the formulation, including the bromide ion.

WARNINGS

Since VECURE causes paralysis of the respiratory muscles, ventilatory support is mandatory for patients treated with this drug until adequate spontaneous respiration is restored.

PRECAUTIONS

General

- **Anaphylactic reactions**

Anaphylactic reactions can occur following the administration of neuromuscular blocking agents. Allergic cross reactivity between muscle relaxants has been reported.

- **Histamine release and histaminoid reactions**

Since neuromuscular blocking agents are known to be capable of inducing histamine release both locally at the site of injection and systemically, the possible occurrence of itching and erythematous reactions at the site of injection and/or generalised histaminoid (anaphylactoid) reactions (see **ADVERSE EFFECTS**) should always be taken into consideration when administering these drugs. Experimental studies with intradermal injection of VECURE have demonstrated that this drug has only a weak capacity for inducing local histamine release. Controlled studies in humans failed to demonstrate any significant rise in plasma levels after intravenous administration of VECURE. Such cases have been reported only rarely, despite the fact that VECURE is now widely used.

- **Cardiovascular effects**

Since VECURE has no cardiovascular effects within the clinical dose range, it does not attenuate bradycardia that may occur due to the use of some types of anaesthetics and opiates or due to vagal reflexes during surgery. The dosage or need for vagolytic drugs may thus be increased in such circumstances.

- **Residual curarisation**

As with other neuromuscular blocking agents, residual curarisation has been reported for VECURE. Factors which could cause residual curarisation after extubation in the postoperative phase (e.g. drug interactions or patient condition) should be considered. If not already used as part of usual clinical practice, the use of sugammadex or another reversal agent should be considered, especially in those cases where residual curarisation is more likely to occur.

Use in neuromuscular syndromes

Extreme caution should be exercised and very small doses used in patients with myasthenia gravis or myasthenic (Eaton-Lambert) syndrome. In such patients, an appropriate neuromuscular monitoring technique and use of a

small test dose may be of value in monitoring the response to administration of muscle relaxants. In cases of neuromuscular disease or after poliomyelitis, similar caution should be exercised.

Hepatic and/or biliary tract disease and/or renal failure/ disease

Since vecuronium is excreted in bile and urine, VECURE should be used with caution in patients with clinically significant hepatic and/or biliary diseases and/or renal failure. In these patient groups prolongation of action has been observed, especially when high doses of vecuronium (0.15 to 0.2 mg/kg bodyweight) were administered in patients with hepatic disease.

Altered circulation time

Conditions associated with slower circulation time, in cardiovascular disease, old age and oedematous states resulting in increased volume of distribution may contribute to a delay in onset time. The duration of action may also be prolonged due to a reduced plasma clearance. Therefore, dosage should not be increased.

Disorders due to other treatments/conditions

Conditions which may increase the neuromuscular blocking effects of VECURE are hypokalaemia (e.g. after severe vomiting, diarrhoea, and diuretic therapy), hypermagnesaemia, hypocalcaemia (after massive transfusions), hypoproteinaemia, dehydration, acidosis, hypercapnia and cachexia.

Electrolyte imbalance and diseases which lead to electrolyte imbalance, e.g. adrenal cortical insufficiency, have been shown to alter neuromuscular blockade. Depending on the nature of the imbalance, either enhancement or inhibition may be expected.

Severe electrolyte disturbances, altered blood pH or dehydration should, therefore, be corrected when possible, prior to administration of VECURE. Monitoring of neuromuscular block by nerve stimulator is useful in all severely ill patients.

Surgery under hypothermia

In operations under hypothermia, the neuromuscular blocking effect of VECURE is increased and the duration is prolonged.

Obesity

Like other neuromuscular blocking agents, VECURE may exhibit a prolonged duration of action and a prolonged spontaneous recovery in obese patients, when the administered doses are calculated on actual body weight.

Burns

Patients with burns are known to develop resistance to non-depolarising agents. It is recommended that the dose is titrated to response.

Central nervous system

VECURE has no known effect on consciousness, the pain threshold or cerebration. Administration must be accompanied by adequate anaesthesia or sedation.

Intensive care unit

In general, following long-term use of neuromuscular blocking agents in the ICU (intensive care unit), prolonged paralysis and/or skeletal muscle weakness has been noted. In order to help preclude possible prolongation of neuromuscular block and/or overdosage, it is strongly recommended that neuromuscular transmission is monitored throughout the use of muscle relaxants. In addition, patients should receive adequate analgesia and sedation. Furthermore, muscle relaxants should be titrated to effect in the individual patients by or under supervision of experienced clinicians who are familiar with their actions and with appropriate neuromuscular monitoring techniques.

Myopathy, after long-term administration of non-depolarising neuromuscular blocking agents in the ICU in combination with corticosteroid therapy, has been reported frequently. Therefore, for patients receiving both the neuromuscular blocking agents and corticosteroids, the period of use of the neuromuscular blocking agent should be limited as much as possible.

Effects on fertility

No adverse effects on fertility or overall reproductive performance were observed in rats treated with intravenous vecuronium bromide at doses up to 15% of the clinical dose on a body surface area basis. Studies with vecuronium bromide alone or in combination with an anaesthetic agent, at doses comparable with clinical dosages, have not been conducted.

Use in pregnancy (Category C)

Vecuronium crosses the placenta but there have been no demonstrated adverse effects in the fetus or the newborn infant. In animal studies intravenous administration of vecuronium bromide to rats during the period of organogenesis at up to maternotoxic doses (about 15% of the recommended clinical dose, based on body surface area) was associated with slightly increased incidences of visceral abnormalities. Similar administration to rabbits at less than maternotoxic doses (about 0.5 to 2% of the recommended clinical dose, based on body surface area) was also associated with increased incidences of visceral abnormalities.

There are insufficient data on the use of VECURE during animal or human pregnancy to assess potential harm to the fetus. VECURE should be given to a pregnant woman only when the attending doctor decides that the benefits outweigh the risks.

Note. Reversal of VECURE induced neuromuscular block may be unsatisfactory in patients receiving magnesium salts for the management of toxaemia of pregnancy because magnesium salts enhance neuromuscular blockade (see **INTERACTIONS WITH OTHER MEDICINES**). In patients, the dosage of VECURE should be reduced and be carefully titrated to twitch response.

Caesarean section

Studies with VECURE, administered in doses up to 0.1 mg/kg, have shown its safety for use in caesarean section.

In several clinical studies VECURE did not affect Apgar score, fetal muscle tonus or cardiorespiratory adaptation. From umbilical cord blood sampling it is apparent that only very little placental transfer of VECURE occurs, the amount being dependent on time from injection to delivery, and which did not lead to the observation of any clinical adverse effect in the newborn infant.

Use in lactation

There are no human data on the use of VECURE during lactation. A decrease in early postnatal survival was observed in rats at a maternal dose of about 15% of the clinical dose, based on body surface area. VECURE should be given to lactating women only when the attending doctor decides that the benefits outweigh the risks.

Paediatric use

A variable, often prolonged, duration of action and potency has been observed in infants. Infants under 1 year of age but older than 7 weeks are moderately more sensitive to VECURE on a mg/kg basis than adults and take about 1.5 times as long to recover (with or without halothane anaesthesia). Use of VECURE should, therefore, be avoided unless the expected benefits outweigh the potential risks (see **INDICATIONS**)

Carcinogenicity

Carcinogenicity studies with vecuronium have not been conducted.

Genotoxicity

Vecuronium was not genotoxic in a series of assays for gene mutation (Salmonella typhimurium), chromosomal damage (rat micronucleus assay) or DNA damage.

Effect on ability to drive and use machines

Since VECURE is used as an adjunct to general anaesthesia, the usual precautionary measures after general anaesthesia should be taken for ambulatory patients.

INTERACTIONS WITH OTHER MEDICINES

The following drugs have been shown to influence the magnitude and/or duration of action of nondepolarising neuromuscular blocking agents.

Effect of other drugs on VECURE

Increased effect

Halogenated volatile anaesthetics potentiate the neuromuscular block of VECURE. The effect only becomes apparent with maintenance dosing (see **DOSAGE AND ADMINISTRATION**). With the presence of these volatile agents, reversal of the block with anticholinesterase inhibitors could also be inhibited.

After intubation with suxamethonium (see **DOSAGE AND ADMINISTRATION**).

Long-term concomitant use of corticosteroids and VECURE in the ICU may result in a prolonged duration of neuromuscular block or myopathy (see **PRECAUTIONS** and **ADVERSE EFFECTS**).

Other drugs,

- Antibiotics: aminoglycoside, lincosamide and polypeptide antibiotics, acylaminopenicillin antibiotics.
- Diuretics, quinidine, magnesium salts, calcium channel blocking agents, lithium salts, cimetidine, lignocaine and acute administration of phenytoin or beta-blocking agents.

Recurarisation has been reported after post-operative administration of aminoglycoside, lincosamide, polypeptide and acylamino-penicillin antibiotics, quinidine and magnesium salts (see **PRECAUTIONS**).

Decreased effect (possible higher dose requirements)

Prior chronic administration of phenytoin or carbamazepine.

Variable effect

Administration of other non-depolarising neuromuscular blocking agents in combination with VECURE may produce attenuation or potentiation of the neuromuscular block, depending on the order of administration and the neuromuscular blocking agent used. Suxamethonium given after the administration of a non-depolarising neuromuscular blocking agent may produce potentiation or attenuation of the neuromuscular blocking agent used.

Effect of VECURE on other drugs

VECURE combined with lignocaine may result in a quicker onset of action of lignocaine.

ADVERSE EFFECTS

Adverse drug reactions (ADRs) are rare (<1/1,000). The most commonly occurring ADRs include changes in vital signs and prolonged neuromuscular block. The most frequently reported ADR during post-marketing surveillance is 'anaphylactic and anaphylactoid reactions' and associated symptoms (reporting frequency <1/100,000). Please see **Table 1**.

Table 1 Vecuronium Bromide for injection

MedDRA SOC	Preferred term[1]	
	Uncommon/rare (<1/100, >1/10,000)	**Very rare** (<1/10,000)
Immune system disorders		Hypersensitivity Anaphylactic reaction Anaphylactoid reaction Anaphylactic shock Anaphylactoid shock
Nervous system disorders		Flaccid paralysis
Cardiac disorder	Tachycardia	
Vascular disorders	Hypotension	Circulatory collapse and shock Flushing
Respiratory, thoracic and mediastinal disorders		Bronchospasm
Skin and subcutaneous tissue disorders		Angioneurotic oedema Urticaria Rash Erythematous rash
Musculoskeletal and connective tissue disorders		Muscular weakness[2] Steroid myopathy[2]
General disorders and administration site conditions	Drug ineffective Decreased drug effect/therapeutic response Increased drug effect/therapeutic response	Face oedema Injection site pain Injection site reaction
Injury, poisoning and procedural complications	Prolonged neuromuscular block Delayed recovery from anaesthesia	Airway complication of anaesthesia

MedDRA version 8
[1]Frequencies are estimates derived from postmarketing surveillance reports and data from the general literature
[2]After long-term use in the ICU
MedDRA: Medical Dictionary for Regulatory Activities
ICU: Intensive Care Unit

Prolonged neuromuscular block.

With non-depolarising agents in general, the most frequent adverse reactions consist of an extension of the pharmacological action beyond the time period needed for surgery and anaesthesia or inadequate reversal of the neuromuscular blockade. This may vary from skeletal muscle weakness to profound and prolonged skeletal muscle paralysis resulting in respiratory insufficiency or apnoea. A few cases of myopathy have been reported after vecuronium was used in the ICU in combination with corticosteroids (see **PRECAUTIONS**).

Inadequate reversal of the neuromuscular blockade is possible with VECURE as with all curariform drugs. These adverse reactions are managed by manual or mechanical ventilation until recovery is judged adequate (see **OVERDOSAGE**).

Anaphylactic reactions

Although very rare, severe anaphylactic reactions to neuromuscular blocking agents, including vecuronum, have been reported. Anaphylactic/anaphylactoid reactions usually comprise of several signs or symptoms, e.g. bronchospasm, cardiovascular changes (e.g. hypotension, tachycardia, circulatory collapse, shock) and cutaneous changes (e.g. angioedema, urticaria). These reactions have, in some cases, been fatal.

DOSAGE AND ADMINISTRATION

VECURE should be administered in carefully adjusted dosage by or under the supervision of experienced clinicians who are familiar with the action and use of these drugs. The drug should not be administered unless facilities for intubation, artificial respiration, oxygen therapy, suction and reversal agents are immediately available.

VECURE should be reconstituted immediately before administration.

Reconstitution

The contents of each vial should be dissolved in water for injections 5 mL.

After reconstitution, VECURE is administered intravenously either as a bolus injection or as a continuous infusion.

When calculating the dose of neuromuscular blocking agents the following factors must be taken into account:

- the anaesthetic technique used, potential interactions with the drugs used before and during anaesthesia, and the condition of the individual patient.

The use of an appropriate neuromuscular monitoring technique is recommended to monitor neuromuscular block and recovery.

Inhalation anaesthetics do potentiate the neuromuscular blocking effects of VECURE. This potentiation, however, becomes clinically relevant in the course of anaesthesia, when the volatile agents have reached the tissue concentrations required for this interaction. Consequently, adjustments with VECURE should be made by administering smaller maintenance doses at less frequent intervals or by using lower infusion rates of VECURE during longer lasting procedures (longer than one hour) under inhalation anaesthesia (see **INTERACTIONS WITH OTHER MEDICINES**).

Initial dose. 0.10 mg/kg provides good to excellent intubating conditions within 2.5 to 3 minutes.

Incremental doses. 0.02 to 0.04 mg/kg.

Skeletal muscle relaxation (to 25% recovery) lasts for 20 to 40 minutes after initial or incremental doses.

With suxamethonium as the intubating agent, initial doses of VECURE 0.04 to 0.06 mg/kg will produce complete neuromuscular block with a similar duration of clinical effect. If suxamethonium is used prior to VECURE, the administration of VECURE should be delayed until the patient starts recovering from suxamethonium induced neuromuscular blockade.

The effect of prior use of other non-depolarising neuromuscular blocking agents on the activity of VECURE has not been studied.

Use by continuous infusion

Infusion of VECURE should be initiated only after early evidence of spontaneous recovery from the loading dose. The infusion of VECURE should be individualised for each patient. The rate of administration should be adjusted to maintain twitch response at 10% of control twitch height or to maintain one to two responses to train of four stimulation.

In adults, the infusion rate required to maintain neuromuscular block at this level, ranges from vecuronium bromide 0.8 to 1.4 microgram/kg/minute. For infants, see Dosage in children. Repeat monitoring of neuromuscular block is recommended since infusion rate requirements vary from patient to patient and with the anaesthetic method used.

Dosage in elderly patients

The same intubation and maintenance doses as for younger adults can be used. However, the duration of action is prolonged in elderly compared to younger subjects due to changes in pharmacokinetic mechanisms. The onset time in elderly is similar to younger adults.

Dosage in children

VECURE is not approved for use in neonates or premature babies. Therefore, no dosing recommendation is made.

Infants under 1 year of age but older than 7 weeks are moderately more sensitive to VECURE on a mg/kg basis than adults (see **PRECAUTIONS - Paediatric use**). Since the onset time of VECURE in these patients is considerably shorter than in adults and children, the use of high intubating doses in general is not required for early development of good intubating conditions. Since the duration of action and recovery time with VECURE is longer in infants than in children and adults, maintenance doses are required less frequently.

Dose requirements for children (2 to 10 years) are higher (see **PHARMACOLOGY**). However, the same intubation and maintenance doses as for adults are usually sufficient. Since the duration of action is shorter in children, maintenance doses are required more frequently.

Although there is very little information on dosage in adolescents, it is advised to use the same dose as in adults, based on the physiological development at this age.

Dosage in overweight and obese patients

When used in overweight or obese patients (defined as patients with a body weight of 30% or more above ideal body weight), doses should be reduced taking into account an ideal body weight.

Higher doses

Should there be a reason for selection of larger doses in individual patients, initial doses ranging from vecuronium bromide 0.15 up to 0.4 mg/kg body weight have been administered for surgery both under halothane and neuroleptic anaesthesia without adverse cardiovascular effects being noted as long as ventilation is properly maintained. The use of these high dosages of VECURE pharmacodynamically decreases the onset time and increases the duration of action.

Compatibility with infusions

When VECURE 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/L:

- sodium chloride 0.9% solution
- glucose 5% solution
- Ringer's solution
- Ringer's solution and glucose 2.5%.

When reconstituted with water for injections, VECURE can also be injected into the line of a running infusion of the following fluids:

- lactated Ringer's solution
- lactated Ringer's solution and glucose 5%
- glucose 5% and sodium chloride 0.9% solution
- Haemaccel
- Dextran 40 5% in sodium chloride 0.9% solution.

As is the case for many other drugs, vecuronium has been shown to be **incompatible** when added to thiopentone or solutions containing thiopentone.

Compatibility studies with other brands of these drugs or with other infusion fluids have not been performed.

If VECURE is administered via the same infusion line that is also used for other drugs, it is important that this infusion line is adequately flushed (e.g. with NaCl 0.9%) between administration of VECURE and drugs for

which incompatibility with VECURE has been demonstrated or for which compatibility with VECURE has not been established.

Neither the reconstituted VECURE in water for injections nor the solutions further diluted with the compatible infusion fluids contain any antimicrobial preservatives. To avoid microbial contamination hazards, the reconstituted or further diluted VECURE injections should be used immediately after preparation and any residue discarded. Do not use VECURE when the solution after reconstitution contains particles or is not clear.

OVERDOSAGE

The possibility of iatrogenic overdosage can be minimised by carefully using an appropriate neuromuscular monitoring technique.

Symptoms

The symptoms of overdosage with a non-depolarising muscle relaxant are those of prolonged paralysis, apnoea, low tidal volume, respiratory depression and/or persistent muscle weakness. Death may follow acute respiratory failure unless treated promptly.

Treatment

1. Supportive measures:

Ventilatory support and sedation.

2. Reversal of neuromuscular blockade:

There are two options for the reversal of neuromuscular block: (1) Sugammadex can be used for reversal of intense (profound) and deep block. The dose of sugammadex to be administered depends on the level of neuromuscular block. (2) An acetylcholinesterase inhibitor (e.g. pyridostigmine, neostigmine or edrophonium), with appropriate vagolytic (e.g. atropine) can be used at reappearance of T2 or at the first signs of clinical recovery and should be administered in adequate doses. Adequate reversal can be judged by the ability of the patient to lift his or her head for at least five seconds or preferably by the use of an appropriate neuromuscular monitoring technique. When administration of an acetylcholinesterase inhibiting agent fails to reverse the neuromuscular effects of VECURE, ventilation must be continued until spontaneous breathing is restored. Overdosage of an acetylcholinesterase inhibitor can be dangerous.

PRESENTATION AND STORAGE CONDITIONS

10 mL vials each containing 10.0 mg sterile lyophilised vecuronium bromide powder for reconstitution, in boxes of 10 vials.

Shelf-life of 2 years when stored below 25° C and protected from light.

To avoid microbial contamination, VECURE should be used without delay once reconstituted and any residue should be discarded.

NAME AND ADDRESS OF THE SPONSOR

Alphapharm Pty Limited

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

ABN 93 002 359 739

www.alphapharm.com.au

POISON SCHEDULE OF THE MEDICINE

S4 (Prescription Only Medicine)

DATE OF FIRST INCLUSION IN THE AUSTRALIAN REGISTER OF THERAPEUTIC GOODS (THE ARTG)

24/05/2011

DATE OF MOST RECENT AMENDMENT

22/04/2015

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