PRODUCT INFORMATION

NORCURON®
(vecuronium bromide)

- Non-proprietary Name: Vecuronium bromide
- Laboratory Code: Org NC 45
- Molecular Structure:

![Molecular Structure Image]

Mol. Formula: $C_{34}H_{57}BrN_2O_4$  
Mol. Weight: 637.73

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

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. Norcuron is available in ampoules and vials containing 4 mg and 10 mg of vecuronium bromide, respectively. Each ampoule or vial also contains citric acid, sodium phosphate, sodium hydroxide and/or phosphoric acid to buffer and adjust the pH and mannitol to make isotonic.

PHARMACOLOGY

Pharmacodynamics

Norcuron 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 end-plate. The antagonism to acetylcholine is inhibited and neuromuscular block is reversed by acetylcholinesterase inhibitors such as neostigmine, edrophonium and pyridostigmine. The neuromuscular block can also be reversed by sugammadex, a Selective Relaxant Binding Agent. The potency of Norcuron is equal to or somewhat greater than that of pancuronium; the duration of neuromuscular blockade produced by Norcuron 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 Norcuron doses. The use of an appropriate neuromuscular monitoring technique may be of benefit in assessing the degree of muscular relaxation.

An initial Norcuron dose of 0.10 mg/kg generally produces first depression of twitch in approximately 1 minute, good or excellent intubation conditions within 2.5 to 3 minutes and maximum neuromuscular blockade within 3 to 5 minutes of injection in most patients. Because of the minimal tendency for cumulation, frequent maintenance doses can be given in succession. Norcuron 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, such as neostigmine, pyridostigmine or edrophonium, in appropriate dosage. Sugammadex can be given for routine reversal at 1-2 post-tetanic counts to reappearance of T₂. Acetylcholinesterase inhibitors can be administered at reappearance of T₂ or at the first signs of clinical recovery.

Paediatric Patients
Infants: The ED₉₅ dose of Norcuron under nitrous oxide in oxygen anaesthesia was found to be approximately the same (approx. 47 μg/kg body weight) 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 Norcuron is longer in infants than in adults. Maintenance doses of Norcuron should therefore be less frequently administered (See also Precautions, Use in Infants and Dosage and Administration).

Children: The ED₉₅ dose of Norcuron under nitrous oxide in oxygen anaesthesia was found to be higher than in adults (0.081 vs 0.043 mg/kg body weight, respectively). In comparison to adults, the duration of action and recovery time with Norcuron in children are in general approximately 30% and 20-30% 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 – 0.15 mg/kg vecuronium, the distribution half-life of vecuronium amounts to 1.2 – 1.4 minutes. Vecuronium is mainly distributed in the extracellular fluid compartment. At steady state, the volume of distribution is 0.16 - 0.51 L.kg⁻¹ in adult patients.

The plasma clearance of vecuronium amounts to 3.0 – 5.6 mL.kg⁻¹.min⁻¹ and its plasma elimination half-life is 36 – 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 Norcuron.

Biliary excretion is the main elimination route. It is estimated that within 24 hours after intravenous administration of Norcuron, 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 Norcuron administration is 20 – 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

Norcuron is a skeletal muscle relaxant for use as an adjunct to general anaesthesia in adults and children for all surgical procedures.

CONTRAINDICATIONS

Norcuron is contraindicated in patients known to be hypersensitive to any of its components including the bromide ion.

Warning

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

PRECAUTIONS

General

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

2) 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 Reactions) should always be taken into consideration when administering these drugs. Experimental studies with intradermal injection of Norcuron have demonstrated that this drug has only a weak capacity for inducing local histamine release. Controlled studies in man failed to demonstrate any significant rise in plasma levels after intravenous administration of Norcuron. Such cases have been reported only rarely, despite the fact that Norcuron is now widely used.

3) Cardiovascular effects
Since Norcuron 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.
4) As with other neuromuscular blocking agents, residual curarization has been reported for Norcuron. Factors which could cause residual curarization after extubation in the postoperative phase (such as drug interactions or patient condition) should also 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 curarization is more likely to occur.

**Carcinogenicity, mutagenicity and impairment of fertility**

Carcinogenicity studies with vecuronium have not been conducted.

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

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 foetus 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 basis) was associated with slightly increased incidences of visceral abnormalities. Similar administration to rabbits at less than maternotoxic doses (about 0.5 - 2% of the recommended clinical dose, based on a body surface area) was also associated with increased incidences of visceral abnormalities.

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

Note: Reversal of Norcuron-induced neuromuscular block may be unsatisfactory in patients receiving magnesium salts for the management of toxemia of pregnancy because magnesium salts enhance the neuromuscular blockade (see Drug Interactions). In patients, the dosage of Norcuron should be reduced and carefully titrated to twitch response.

**Caesarean section**

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

In several clinical studies Norcuron did not affect Apgar score, foetal muscle tonus or cardiorespiratory adaptation. From umbilical cord blood sampling it is apparent that only very little placental transfer of Norcuron 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 new-born.

**Use in Lactation**

There are no human data on the use of Norcuron 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. Norcuron should be given to lactating women only when the attending physician decides that the benefits outweigh the risks.
Use in Infants /Use in children

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 Norcuron on a mg/kg basis than adults and take about 1½ times as long to recover (with or without halothane anaesthesia). Use of Norcuron should therefore be avoided unless the expected benefits outweigh the potential risks (See also Indications).

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, Norcuron 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 – 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 Norcuron are: hypokalaemia (e.g. after severe vomiting, diarrhoea, and diuretic therapy), hypermagnesaemia, hypocalcaemia (after massive transfusions), hypoproteinaemia, dehydration, acidosis, hypercapnia, cachexia.

Electrolyte imbalance and diseases which lead to electrolyte imbalance, such as 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 Norcuron. 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 Norcuron is increased and the duration is prolonged.

Obesity

Like other neuromuscular blocking agents, Norcuron 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.

C.N.S.

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

I.C.U.

In general, following long term use of neuromuscular blocking agents in the ICU, 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 ability to drive and use machines

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

Drug Interactions

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

Effect of other drugs on Norcuron

Increased effect:
Halogenated volatile anaesthetics potentiate the neuromuscular block of Norcuron. The effect only becomes apparent with maintenance dosing (see also 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 Norcuron in the ICU may result in a prolonged duration of neuromuscular block or myopathy (see also Precautions and Adverse Reactions).

Other drugs:
• antibiotics: aminoglycoside, lincosamide and polypeptide antibiotics, acylamino-penicillin antibiotics.
• diuretics, quinidine, magnesium salts, calcium channel blocking agents, lithium salts, cimetidine, lignocaine and acute administration of phenytoin or β-blocking agents.

Recurarization 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 Norcuron 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 Norcuron on other drugs**
Norcuron combined with lignocaine may result in a quicker onset of action of lignocaine.

**ADVERSE REACTIONS**

Adverse Drug Reactions (ADRs) are rare (< 1/1000). 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 refer to below table.

<table>
<thead>
<tr>
<th>MedDRA SOC</th>
<th>Preferred term ¹</th>
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<tr>
<td><strong>Uncommon / rare</strong> (&lt;1/100, &gt; 1/10 000)</td>
<td><strong>Very rare</strong> (&lt;1/10 000)</td>
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<td>Circulatory collapse and shock</td>
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<td>Flushing</td>
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<td>Respiratory, thoracic and mediastinal disorders</td>
<td>Bronchospasm</td>
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| Skin and subcutaneous tissue disorders | Angioneurotic oedema  
Urticaria  
Rash  
Erythematous rash |
|-------------|------------------|
| Musculoskeletal and connective tissue disorders | Muscular weakness²  
Steroid myopathy² |
| General disorders and administration site conditions | Drug ineffective  
Decreased drug effect/ therapeutic response  
Increased drug effect / therapeutic response |
| 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 post-marketing surveillance reports and data from the general literature.
² after long-term use in the ICU

**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 Norcuron was used in the ICU in combination with corticosteroids (see Precautions).

Inadequate reversal of the neuromuscular blockade is possible with Norcuron as with all curariform drugs. These adverse reactions are managed by manual or mechanical ventilation until recovery is judged adequate (See also Overdosage).

**Anaphylactic reactions**

Although very rare, severe anaphylactic reactions to neuromuscular blocking agents, including Norcuron, 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**

Norcuron 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.

Norcuron should be reconstituted immediately before administration.

**Reconstitution:**

Norcuron 4mg: The contents of each ampoule of Norcuron 4mg should be dissolved in 1 mL water for injections.

Norcuron 10mg: The contents of each vial should be dissolved in 5mL water for injections.
After reconstitution, Norcuron 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 Norcuron. 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 Norcuron should be made by administering smaller maintenance doses at less frequent intervals or by using lower infusion rates of Norcuron during longer lasting procedures (longer than 1 hour) under inhalation anaesthesia (see Drug Interactions).

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

Incremental doses: 0.02 - 0.04 mg/kg.

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

With suxamethonium as the intubating agent, initial doses of 0.04-0.06 mg/kg of Norcuron will produce complete neuromuscular block with a similar duration of clinical effect. If suxamethonium is used prior to Norcuron the administration of Norcuron 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 Norcuron has not been studied.

**Use by continuous infusion**

Infusion of Norcuron should be initiated only after early evidence of spontaneous recovery from the loading dose. The infusion of Norcuron 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 1 to 2 responses to train of four stimulation.

In adults, the infusion rate required to maintain neuromuscular block at this level ranges from 0.8 to 1.4 µg vecuronium bromide per kg per min. 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**

Norcuron 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 Norcuron on a mg/kg basis than adults (See also Precautions, Use in Infants). Since the onset time of Norcuron 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 Norcuron is longer in infants than in children and adults, maintenance doses are required less frequently.

Dose requirements for children (2 – 10 years) are higher (see Pharmacodynamics). 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 0.15 mg up to 0.4 mg vecuronium bromide per 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 Norcuron pharmacodynamically decreases the onset time and increases the duration of action.

**Compatibility with Infusions**

When Norcuron 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:
- 0.9% NaCl solution
- 5% glucose solution
- Ringer’s solution
- Ringer’s solution 2.5% glucose

When reconstituted with water for injections, Norcuron can also be injected into the line of a running infusion of the following fluids:
- Lactated Ringer’s solution
- Lactated Ringer’s solution and 5% glucose
- 5% glucose and 0.9% NaCl solution
- Haemaccel
- Dextran-40 5% in 0.9% NaCl solution

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

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

If Norcuron 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 0.9 % NaCl) between administration of Norcuron and drugs for which incompatibility with Norcuron has been demonstrated or for which compatibility with Norcuron has not been established.
Neither the reconstituted Norcuron 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 Norcuron injections should be used immediately after preparation and any residue discarded. Do not use Norcuron 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.

Clinical Features

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.

Management

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 5 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 Norcuron, ventilation must be continued until spontaneous breathing is restored. Overdosage of an acetylcholinesterase inhibitor can be dangerous.

PRESENTATION

2 mL ampoules each containing 4.0 mg sterile lyophilised vecuronium bromide with a 1 mL ampoule of solvent (water for injections) for each ampoule of Norcuron. Boxes of 10 or 50 ampoules of Norcuron.

5mL vials each containing 10.0 mg sterile lyophilised vecuronium bromide in boxes of 10 vials (without solvent).

Storage Conditions

Norcuron 4mg in ampoules: Shelf life 3 years when stored below 25°C and protected from light.
Norcuron 10mg in vials: Shelf life 2 years when stored below 25°C and protected from light.

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

POISON SCHEDULE

S4 - Prescription Only Medicine
SPONSOR

Schering-Plough Pty Limited
Level 4, 66 Waterloo Road
North Ryde NSW 2113
Australia

Date of TGA Approval: 19 September 2007
Date of most recent amendment: 28 January 2010