



SAGENT Pharmaceuticals™

VECURONIUM

CATALOG

VECURONIUM Bromide for Injection

SAGENT offers the Injectables Excellence™ you deserve

- Available in:
 - 10 mg per vial
 - 20 mg per vial
 - LATEX-FREE
 - Preservative-free
 - Discover **PreventIV Measures™** packaging features:
 - Easy-to-read drug name and dosage strength
 - Bar codes included on the vials and cartons for ease of scanning
 - Unique label design
 - Paralyzing Agent warning flag on the cap, label and carton designed to caution all healthcare workers who handle the product
- Enhanced packaging and labeling designed to promote safety and help reduce medication errors



Please see full prescribing information for VECURONIUM Bromide for Injection, enclosed.



Discover Injectables Excellence™

VECURONIUM Bromide for Injection



Innovator Product Name: NORCURON® (NORCURON is a registered trademark of Organon USA, Inc.)

| NDC Number | Description | Strength | Vial Closure | Unit of Sale | Bar Coded |
|--------------|-------------|----------|--------------|--------------|-----------|
| 25021-657-10 | Glass Vial | 10 mg | 20 mm | 10 Vials | ✓ |
| 25021-658-20 | Glass Vial | 20 mg | 20 mm | 10 Vials | ✓ |

This SAGENT product meets stringent FDA requirements and is AP rated, LATEX-FREE and preservative-free.

To order, or for more information about discovering Injectables Excellence™ with SAGENT, contact your sales representative, call 1-866-625-1618 or visit www.SagentPharma.com.

Listening. Responding. Delivering. That's Injectables Excellence.™ That's SAGENT Pharmaceuticals.

VECURONIUM Bromide for Injection

INDICATIONS

VECURONIUM Bromide for Injection is indicated as an adjunct to general anesthesia, to facilitate endotracheal intubation and to provide skeletal muscle relaxation during surgery or mechanical ventilation.

IMPORTANT SAFETY INFORMATION

WARNING
THIS DRUG SHOULD BE ADMINISTERED BY ADEQUATELY TRAINED INDIVIDUALS FAMILIAR WITH ITS ACTIONS, CHARACTERISTICS, AND HAZARDS.

CONTRAINDICATIONS

VECURONIUM Bromide for Injection is contraindicated in patients known to have a hypersensitivity to it.

WARNINGS

- VECURONIUM Bromide for Injection should be administered in carefully adjusted dosage by or under the supervision of experienced clinicians who are familiar with its actions and the possible complications that might occur following its use.
- VECURONIUM Bromide for Injection should not be administered unless facilities for intubation, artificial respiration, oxygen therapy, and reversal agents are immediately available. The clinician must be prepared to assist or control respiration.
- To reduce the possibility of prolonged neuromuscular blockade and other possible complications that might occur following long-term use in the ICU, VECURONIUM Bromide for Injection or any other neuromuscular blocking agent should be administered in carefully adjusted doses by or under the supervision of experienced clinicians who are familiar with its actions and who are familiar with appropriate peripheral nerve stimulator muscle monitoring techniques.
- Small doses of VECURONIUM Bromide for Injection may have profound effects in patients who are known to have myasthenia gravis or the myasthenic (Eaton-Lambert) syndrome. In such patients, a peripheral nerve stimulator and use of a small test dose may be of value in monitoring the response to administration of muscle relaxants.
- Severe anaphylactic reactions to neuromuscular blocking agents, including VECURONIUM Bromide for Injection, have been reported. These reactions have in some cases been life-threatening and fatal. Due to the potential severity of these reactions, the necessary precautions, such as the immediate availability of appropriate emergency treatment, should be taken. Precautions should also be taken in those individuals who have had previous anaphylactic reactions to other neuromuscular blocking agents since cross-reactivity between neuromuscular blocking agents, both depolarizing and non-depolarizing, has been reported in this class of drugs.

PRECAUTIONS

- VECURONIUM Bromide for Injection is well tolerated without clinically significant prolongation of neuromuscular blocking effect in patients with renal failure who have been optimally prepared for surgery by dialysis.
- Conditions associated with slower circulation time in cardiovascular disease, old age, edematous states resulting in increased volume of distribution may contribute to delay in time of onset of VECURONIUM Bromide for Injection; therefore, dosage should not be increased.
- Experience in patients with cirrhosis or cholestasis has revealed prolonged recovery time in keeping with the role the liver plays in vecuronium metabolism and excretion.
- In the intensive care unit, long-term use of neuromuscular blocking drugs to facilitate mechanical ventilation may be associated with prolonged paralysis and/or skeletal muscle weakness, that may be first noted during attempts to wean such patients from the ventilator.
- In the intensive care unit, appropriate monitoring, with the use of a peripheral nerve stimulator to assess the degree of neuromuscular blockade is recommended to help preclude possible prolongation of the blockade.

- Patients with severe obesity or neuromuscular disease may pose airway and/or ventilatory problems requiring special care before, during and after the use of neuromuscular blocking agents such as VECURONIUM Bromide for Injection.
- Prior administration of succinylcholine may enhance the neuromuscular blocking effect of VECURONIUM Bromide for Injection and its duration of action.
- Use of volatile inhalational anesthetics such as enflurane, isoflurane, and halothane with VECURONIUM Bromide for Injection will enhance neuromuscular blockade.
- Unexpected prolongation of neuromuscular block should be considered a possibility when antibiotics such as aminoglycosides, tetracyclines, bacitracin, polymyxin B, colistin, and sodium colistimethate are used in conjunction with VECURONIUM Bromide for Injection.
- Reconstituted vecuronium, which has an acid pH, should not be mixed with alkaline solutions, such as thiopental, in the same syringe or administered simultaneously during intravenous infusion through the same needle or through the same intravenous line.
- VECURONIUM Bromide for Injection should be given to a pregnant woman only if clearly needed.
- It is not known whether this drug is excreted in human milk.
- The safety and effectiveness of VECURONIUM Bromide for Injection in pediatric patients less than 7 weeks of age have not been established.

ADVERSE REACTIONS

- The most frequent adverse reaction to nondepolarizing blocking agents as a class consists of an extension of the drug's pharmacological action beyond the time period needed. This may vary from skeletal muscle weakness to profound and prolonged skeletal muscle paralysis resulting in respiration insufficiency or apnea.
- Inadequate reversal of the neuromuscular blockade is possible with VECURONIUM Bromide for Injection as with all curariform drugs. These adverse reactions are managed by manual or mechanical ventilation until recovery is judged adequate.
- Prolonged to profound extensions of paralysis and/or muscle weakness as well as muscle atrophy have been reported after long-term use to support mechanical ventilation in the intensive care unit.
- The administration of VECURONIUM Bromide for Injection has been associated with rare instances of hypersensitivity reactions (bronchospasm, hypotension, and/or tachycardia, sometimes associated with acute urticaria or erythema).
- There have been post-marketing reports of severe allergic reactions (anaphylactic and anaphylactoid reactions) associated with the use of neuromuscular blocking agents, including VECURONIUM Bromide for Injection.

OVERDOSAGE

- The possibility of iatrogenic overdose can be minimized by carefully monitoring muscle twitch response to peripheral nerve stimulation.
- Excessive doses of VECURONIUM Bromide for Injection produce enhanced pharmacological effects. A peripheral nerve stimulator may be used to assess the degree of residual neuromuscular blockade from other causes of decreased respiratory reserve. The primary treatment of respiratory depression is maintenance of a patent airway and manual or mechanical ventilation until complete recovery of normal respiration is assured.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088. Please see full prescribing information for VECURONIUM Bromide for Injection.

LATEX-FREE = There is no natural rubber latex in the vial container closure or label adhesive in this SAGENT product.

NORCURON is a registered trademark of Organon USA, Inc. All other trademarks used herein are the property of Sagent Pharmaceuticals, Inc.

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