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- Duration of reversal comparable to that of neostigmine—66 minutes versus 76 minutes for neostigmine.\(^1,^2\)

- Significantly fewer muscarinic side effects and lower atropine requirement than with neostigmine—edrophonium, 0.5 mg/kg, with only 7 \(\mu g/kg\) atropine, produced minimal change in heart rate or mean arterial pressure compared to noticeable changes in both indexes following neostigmine, 0.04 mg/kg, using twice the atropine dose (15 \(\mu g/kg\)).\(^1,^2\)

- May be the preferred reversal agent for atracurium and vecuronium ‘...compared with neostigmine, edrophonium has a more complete spectrum of atracurium reversal characteristics, and...antagonizes more rapidly residual atracurium-induced neuromuscular blockade.’\(^3\)

‘Edrophonium may in fact be the preferred reversal agent for routine use with [vecuronium], having the advantages that restoration of voluntary muscle function is very rapid, and that the relatively small dose of atropine required minimizes the unwanted side-effects of this drug.’\(^4\)

*Note: When duration of action is adjusted for differences in onset of action, the relative durations are 65 minutes for edrophonium, and 69 minutes for neostigmine.


Please see use information on next page.
Anaquest introduces Enlon (edrophonium chloride injection, USP)

DESCRIPTION
ENLON (edrophonium chloride injection, USP) is a rapid acting cholinergic (anticholinesterase inhibitor). Chemically edrophonium chloride is ethyl (m-hydroxyphenyl) dimethylammonium chloride and its structural formula is:

\[
\begin{array}{c}
\text{HO} \quad \text{C} \quad \text{C} \quad \text{N} \quad \text{(CH}_3)_2 \\
\end{array}
\]

\[
\text{Cl}^- \quad \text{C} \quad \text{H}_2 \text{O} \quad \text{C} \quad \text{C} \quad \text{N} \quad \text{(CH}_3)_2
\]

ENLON contains in each mL of sterile solution:

10 mg edrophonium chloride compound with 0.4% phenol and 0.3% sodium sulfate as preservative, buffered with sodium citrate and citric acid, its pH is adjusted to approximately 5.4.

CLINICAL PHARMACOLOGY
ENLON (edrophonium chloride injection, USP) activates neuromuscular transmission primarily by inhibiting or inactivating acetylcholinesterase. By inactivating the acetylcholinesterase enzyme, acetylcholine is not hydrolyzed by acetylcholinesterase and is thereby allowed to accumulate. The accumulation of acetylcholine at the sites of cholinergic transmission facilitates transmission of impulses across the myoneural junction.

INDICATIONS AND USAGE
ENLON (edrophonium chloride injection, USP) is recommended as a reversal agent or antagonist of nondepolarizing muscle relaxants such as tubocurarine, mivacurium, atracurium, vecuronium, or pancuronium. It is not effective against depolarizing relaxants such as suxamethonium and decamethonium. It is also useful if used adductively in the treatment of respiratory depression caused by excessive overdose. ENLON is recommended for use in the differential diagnosis of myasthenia gravis. It is now accepted that the diagnosis of myasthenia gravis is confirmed only after evaluation of treatment requirements of the disease and for evaluating emergency treatment in myasthenic crises. It is not recommended for maintenance therapy in myasthenia gravis.

CONTRAINDICATIONS
ENLON (edrophonium chloride injection, USP) is not to be used in patients with known hypersensitivity to anticholinesterase agents, or in patients having urinary obstructions of mechanical type.

WARNINGS
It is recommended that 1 mg atropine sulfate be made available for immediate use to counteract any severe cholinergic reaction. ENLON (edrophonium chloride injection, USP) should be used with caution in patients with bronchial asthma or cardiac dysrhythmias. Transient bradycardia may occur and be relieved by atropine sulfate. Intravenous administration of cardiotonic substances should be carefully administered and the dosage of anticholinesterase drugs reduced or withheld until the patient again becomes sensitive to atropine.

Drug Interactions: The drug should not be administered prior to the administration of any nondepolarizing muscle relaxant. The drug should be administered as full-dose anticholinesterase drugs reduced or withheld until the patient again becomes sensitive to atropine.

Pregnancy Category C: It is not known whether ENLON (edrophonium chloride injection, USP) can cause fetal harm when administered to a pregnant woman, or can affect reproduction capacity, since there have been no adequate and well controlled studies in humans.

Labor and Delivery: The effect of ENLON on the mother and fetus, or on the duration of labor or delivery, or on the possibilities that forceps delivery or other interventions or resuscitation of the newborn will be necessary is not known. The effect of the drug on the later growth, development and functional maturation of the child is also unknown.

Nursing Mothers: The safety of ENLON during lactation in humans has not been established.

ADVERSE REACTIONS
A patient in myasthenic crisis, being treated with ENLON (edrophonium chloride injection, USP) should be observed for bradycardia or cardiac standstill and cholinergic reactions if an overdose is given. Reactions common to anticholinesterase agents such as edrophonium chloride are:

Cardiovascular: arrhythmias (especially bradycardia), fall in output leading to hypotension;

Respiratory: increased tracheobronchial secretions, laryngospasm, bronchial constriction and respiratory muscle paralysis;

Neurologic: convulsions, dysarthria, dysphonia, and dysphagia;

Gastrointestinal: vomiting, diarrhea, increased peristalsis, increased gastric and intestinal secretions, diarrhoea, abdominal cramps;

Miscellaneous: weakness and fasciculations;

Miscellaneous: increased urinary frequency, diaphoresis, increased lacrimation, pupillary constriction, diaphoresis, and conjunctival hyperemia.

OVERDOSAGE
Muscarinic-like symptoms (nausea, vomiting, diarrhea, sweating, increased bronchial and salivary secretions and bradycardia) may appear with overdosage (cholinergic crisis). ENLON (edrophonium chloride injection, USP) may be managed by the use of atropine. Obstruction of the airway by bronchial secretions can arise and may be managed with suction (especially if tracheostomy has been performed) and by the use of atropine. Signs of atropine overdosage such as dry mouth, flush and tachycardia should be avoided as tachycardia and bronchial plugs may form. Should edrophonium chloride overdose occur:

1. Maintain respiratory exchange.
2. Monitor cardiac function.

Appropriate measures should be taken if convulsions or shock are present.

DOSAGE AND ADMINISTRATION
The recommended adult intravenous injection for antagonism of neuromuscular block:

- 0.1 mL (10 mg) slowly within a period of 30 to 45 seconds. The dose may be repeated to a maximum total dose of 4 mL (40 mg). Its onset of action is manifest within 20 to 60 seconds after injection. Response should be monitored carefully and assisted ventilation should always be employed. When given to counteract muscle relaxant overdosage, the dose effect on respiration should be observed prior to repeat dosages and assisted ventilation should be employed.

ENLON (edrophonium chloride injection, USP) Test in Differential Diagnosis of Myasthenia Gravis:

Adults: Intravenous injection of 0.5 mL (5 mg) of ENLON should be administered slowly within a period of 30 to 45 seconds. The onset of action is manifest within 15 to 30 seconds.

The test dose of ENLON should be repeated 60 minutes later. If there is no response within 60 minutes, the test may be repeated one hour after the initial dose.

Intramuscular Dose: Intramuscularly inject 0.1 mL (10 mg) of ENLON. If no reaction occurs after 45 seconds, the test may be repeated one hour after the initial dose.

ENLON (edrophonium chloride injection, USP) Test to Evaluate Treatment Requirements in Myasthenia Gravis:

The test dose of ENLON should be repeated 45 seconds after oral intake of the drug being used to treat the disease. If there is no response within 45 seconds, the test may be repeated one hour after the initial dose. The dose of ENLON may be increased to 0.6 mL (60 mg) until the test is negative.

Children:

- Intravenous injection of 0.1 mL (1 mg) of ENLON. If there is no response within 45 seconds, the dose may be repeated to a maximum total dose of 0.5 mL (5 mg). The recommended dose in infants is 0.05 mL (0.5 mg).

Children with seizure disorders (0.1 mg/kg body weight) should be observed for change. The remaining dose may be repeated one hour after the initial dose. If the patient is apneic, achieve ventilatory exchange immediately with inadequate ventilatory exchange, and unpredictable response to medication If the patient is apneic, achieve ventilatory exchange immediately with inadequate ventilatory exchange, and unpredictable response to medication If, after one-half hour, there is no response, discontinue all anticholinesterase drugs. Controlled ventilation can be achieved by tracheostomy with assisted respiration.

ENLON (edrophonium chloride injection, USP) Test in Crisis:

Crisis in the myasthenic patient is characterized as a state of severe respiratory distress with inadequate ventilatory exchange and unobtainable breath sounds. If the patient is apneic, achieve ventilatory exchange immediately with inadequate ventilatory exchange, and unpredictable response to medication If, after one-half hour, there is no response, discontinue all anticholinesterase drugs. Controlled ventilation can be achieved by tracheostomy with assisted respiration.

SUPPLIED
ENLON (edrophonium chloride injection, USP) is supplied in a vial containing 0.1 mL (1 mg) of ENLON. It is available in quantities of 100 vials or 500 vials. It is supplied in a vial containing 0.1 mL (1 mg) of ENLON. It is available in quantities of 100 vials or 500 vials.
Because the longer procedure raises the surgical risk...

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Please see following page for brief summary of prescribing information.
I experienced DRUG INTERACTION: ADVERSE REACTIONS:

Neuromuscular the most frequently noted adverse reactions signs before Pavulon, the administration patients receiving potent volatile inhalational anesthetics been reported. Anticholinergic premedication is used. Manual or mechanical ventilation until recovery is judged adequate (pancuronium bromide) as with all curariform the neuromuscular blockade by anticholinesterase agents has also been observed surgery and anesthesia

PRECAUTIONS:
magnesium salts enhance neuromuscular may be indicated, in such cases

USAGE IN PREGNANCY:
Pavulon in such

WARNINGS:
Drug or to the bromide ion

Pavulon may be antagonized by acetylcholine, anticholinesterases and

Pavulon is a non-depolarizing neuromuscular blocking agent possessing all of the characteristic pharmacological actions of this class of drugs curariform on the myoneural junction.

Pavulon (pancuronium bromide) is antagonized by acetylcholine, anticholinesterases and potassium ion. Its action is increased by inhalational anesthetics such as halothane, diethyl ether, enflurane and methoxyflurane, as well as gamma, magnesium salts, hypokalemia, some carci- omas, and certain antibiotics such as neomycin, streptomycin, chloramphenicol, kanamycin, gentami- cin and bacitracin. The action of Pavulon may be altered by dehydration, electrolyte imbalance, acid-base imbalance, renal disease, and concomitant administration of other neuromuscular agents.

CONTRAINDICATIONS: Pavulon is contraindicated in patients known to be hypersensitive to the drug or to the bromide ion.

ADMINISTRATION: Pavulon 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. The drug 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.

In patients who are known to have myasthenia gravis, small doses of Pavulon may have profound effects. A peripheral nerve stimulator is especially valuable in assessing the effects of Pavulon in such patients.

Usage in Pregnancy: The safe use of pancuronium bromide has not been established with respect to the possible adverse effects upon fetal development. Therefore, it should not be used in women of childbearing potential and particularly during early pregnancy unless, in the judgment of the physician, the potential benefits outweigh the unknown hazards.

Pavulon may be used in operative obstetrics (Cesarian section) or reversal of pancuronium bromide may be unsatisfactory in patients receiving magnesium sulfate for toxemia of pregnancy, because magnesium salts enhance neuromuscular blockade. Dosage should usually be reduced, as indicated, in such cases.

Precautions: Although Pavulon has been used successfully in many patients with pre-existing pulmonary, hepatic, or renal disease, caution should be exercised in these situations. This is particularly true of renal disease since a major portion of administered Pavulon is excreted unchanged in the urine.

Adverse Reactions: Neuromuscular-the most frequently noted adverse reactions consist primarily of extension of the drug's pharmacological actions beyond the time period needed for surgery and anesthesia. This may vary from skeletal muscle weakness to profound and prolonged skeletal muscle relaxation resulting in respiratory insufficiency or even inadequate reversal of the neuromuscular blockade by anticholinesterase agents has also been observed with Pavulon (pancuronium bromide) as with all curariform drugs. These adverse reactions are managed by manual or mechanical ventilation until recovery is judged adequate.

Cardiovascular: A slight increase in pulse rate is frequently noted.

Gastrointestinal: Salivation is sometimes noted during very light anesthesia, especially if no anticholinergic premedication is used.

Skin: An occasional transient rash is noted accompanying the use of Pavulon.

Respiratory: One case of wheezing, responding as that used for endotracheal intubation. If succinylcholine is used before Pavulon, the administration of Pavulon should be delayed until the succinylcholine shows signs of wearing off.

Dosage and Administration: Pavulon should be administered only by or under the supervision of experienced clinicians. Dosage Must Be Individualized. See package insert for suggested dosages.

CAUTION: Federal law prohibits dispensing without prescription.

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