Published on: 10 Jul 2014

URIVOID Tablets (Bethanechol chloride)

Composition

Each uncoated tablet contains:
Bethanechol chloride USP.....25 mg

Dosage Form

Oral tablet

Pharmacology

▶ Pharmacodynamics

Mechanism of Action
Bethanechol is a synthetic choline ester of carbamic acid which possesses a significant acetylcholine-like activity. It is active after oral administration. As a consequence of the very slow hydrolysation by acetylcholinesterase bethanechol has a prolonged action as has been demonstrated in the urinary tract. The onset of action occurs after oral administration within an hour.
The major pharmacological effects of bethanechol result from interaction of the drug with muscarinic receptor sites of smooth muscles, especially those of the urinary bladder and gastrointestinal tract. In addition, minor but important nicotinic effects have been noted.
Effects on the GI and urinary tracts sometimes appear within 30 minutes after oral administration of bethanechol chloride, but more often 60 to 90 minutes are required to reach maximum effectiveness. Following oral administration, the usual duration of action of bethanechol is one hour, although large doses (300 to 400 mg) have been reported to produce effects for up to six hours. Subcutaneous injection produces a more intense action on bladder muscle than does oral administration of the drug.
Because of the selective action of bethanechol, nicotinic symptoms of cholinergic stimulation are usually absent or minimal when orally or subcutaneously administered in therapeutic doses, while muscarinic effects are prominent. Muscarinic effects usually occur within 5 to 15 minutes after subcutaneous injection, reach a maximum in 15 to 30 minutes, and disappear within two hours. Doses that stimulate micturition and defecation and increase peristalsis do not ordinarily stimulate ganglia or voluntary muscles. Therapeutic test doses in normal human subjects have little effect on heart rate, blood pressure or peripheral circulation. Bethanechol chloride does not cross the blood-brain barrier because of its charged quaternary amine moiety. The metabolic rate and mode of excretion of the drug have not been elucidated.
A clinical study was conducted on the relative effectiveness of oral and subcutaneous doses of bethanechol chloride on the stretch response of bladder muscle in patients with urinary retention. Results showed that 5 mg of the drug given subcutaneously stimulated a response that was more rapid in onset and of larger magnitude than an oral dose of 50 mg, 100 mg, or 200 mg. All the oral doses, however, had a longer duration of effect than the subcutaneous dose. Although the 50 mg oral dose caused little change in

intravesical pressure in this study, this dose has been found in other studies to be clinically effective in the rehabilitation of patients with decompensated bladders.

Indications

URIVOID is indicated for the treatment of acute postoperative and postpartum non-obstructive (functional) urinary retention and neurogenic atony of the urinary bladder with retention.
Reflux oesophagitis; treatment of reflux associated with decreased pressure of the lower oesophageal sphincter or delayed gastric emptying.

Dosage And Administration

Administration orally by tablets.
Adults: 10mg – 25mg three or four times daily, taken half an hour before food. Occasionally it may be necessary to initiate therapy with a 50 mg dose. Caution should be advised when administered to elderly patient.
Children: The experience with children is limited therefore no recommended dose is given.

Contraindications

Hypersensitivity to bethanechol chloride tablets, hyperthyroidism, peptic ulcer, latent or active bronchial asthma, pronounced bradycardia or hypotension, vasomotor instability, coronary artery disease, epilepsy and parkinsonism.
Bethanechol chloride should not be employed when the strength or integrity of the gastrointestinal or bladder wall is in question, or in the presence of mechanical obstruction; when increased muscular activity of the gastrointestinal tract or urinary bladder might prove harmful, as following recent urinary bladder surgery, gastrointestinal resection and anastomosis, or when there is possible gastrointestinal obstruction; in bladder neck obstruction, spastic gastrointestinal disturbances, acute inflammatory lesions of the gastrointestinal tract, or peritonitis; or in marked vagotonia.

Warnings And Precautions

▶ General

A severe cholinergic reaction is likely if bethanechol chloride is administered IV or IM. This reaction has also rarely occurred in cases of hypersensitivity or overdose.
In urinary retention, if the sphincter fails to relax as bethanechol contracts the bladder, urine may be forced up the ureter into the kidney pelvis. If there is bacteriuria, this may cause reflux infection.

▶ Drug Interactions

Pharmacological interactions may occur with the following when bethanechol is administered. Quinidine and procainamide which may antagonise cholinergic effects, cholinergic drugs which may have an additive effect, particularly cholinesterase inhibitors. When administered to patients receiving ganglionic blocking compounds, a critical fall in blood pressure may occur preceded by severe abdominal symptoms.

▶ Effects on ability to drive and use machines

In some cases the ability to drive and operate machinery may be impaired.

▶ Information for Patients

URIVOID tablets should preferably be taken one hour before or two hours after meals to avoid nausea or vomiting. Dizziness, lightheadedness or fainting may occur, especially when getting up from a lying or sitting position.

▶ Pregnancy

Pregnancy Category C
Animal reproduction studies have not been conducted with bethanechol chloride. It is also not known whether bethanechol chloride can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. URIVOID should be given to a pregnant woman only if clearly needed.

▶ Lactation

It is not known whether this drug is secreted in human milk. Because many drugs are secreted in human milk and because of the potential for serious adverse reactions from bethanechol chloride in nursing infants, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

▶ Paediatric Use

Safety and effectiveness in paediatric patients have not been established.

Undesirable Effects

Adverse reactions are rare following oral administration of bethanechol, but are more common following subcutaneous injection. Adverse reactions are more likely to occur when dosage is increased.
The following adverse reactions have been observed: Body as a Whole. malaise; Digestive: abdominal cramps or discomfort, colicky pain, nausea and belching, diarrhea, borborygmi, salivation; Renal: urinary urgency; Nervous System: headache; Cardiovascular: a fall in blood pressure with reflex tachycardia, vasomotor response; Skin: flushing producing a feeling of warmth, sensation of heat about the face, sweating; Respiratory: bronchial constriction, asthmatic attacks; Special Senses: lacrimation, miosis.
Causal Relationship Unknown
The following adverse reactions have been reported, and a causal relationship to therapy with bethanechol has not been established: *Body as a Whole:* malaise; *Nervous System:* seizures.

Overdosage

The symptoms of overdose include nausea, salivation, lachrymation, eructation, involuntary defecation and urination, transient dyspnoea, palpitation, bradycardia and peripheral vasodilation leading to hypertension, transient heart block and a feeling of constriction under the sternum.
Emergency Procedure: The stomach should be emptied by aspiration or lavage.
Give atropine sulphate 1-2mg intravenously, intramuscularly or subcutaneously to control muscarinic effects. The dose may be repeated every 2-4 hours as necessary. Supportive treatment includes intravenous administration of diazepam 5-10mg: muscle twitching may be controlled by small doses of tubocararine (together with assisted respiration): oxygen may be required.

Storage And Handling Instructions

Keep out of reach of children and away from direct heat or light sources.

Store below 25ºC.

Packaging Information

URIVOID: Strip of 10 tablets

Last Updated: *Dec 2013*

Last Reviewed: *Apr 2016*

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