

PRESCRIBING INFORMATION

Pr **DUVOID**[®]
bethanechol chloride

10mg, 25mg and 50mg Tablets, USP

Parasympathomimetic

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ACTIONS AND CLINICAL PHARMACOLOGY

Bethanechol acts principally by producing the effects of stimulation of the parasympathetic nervous system. It increases the tone of the detrusor urinae muscle, usually producing a contraction sufficiently strong to initiate micturition and empty the bladder. It stimulates gastric motility, increases gastric tone, and often restores rhythmic peristalsis.

Stimulation of the parasympathetic nervous system releases acetylcholine at the nerve endings. When spontaneous stimulation is reduced and therapeutic intervention is required, acetylcholine can be given, but it is rapidly hydrolyzed by cholinesterase, and its effects are transient. Bethanechol is not destroyed by cholinesterase and its effects are more prolonged and predictable than those of acetylcholine.

It has predominant muscarinic action and only feeble nicotinic action. 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.

INDICATIONS AND CLINICAL USE

The treatment of acute postoperative and postpartum nonobstructive (functional) urinary retention and for neurogenic atony of the urinary bladder with retention.

CONTRAINDICATIONS

Hyperthyroidism, pregnancy, lactation, peptic ulcer, latent or active bronchial asthma, pronounced bradycardia or hypotension, vasomotor instability, coronary artery disease, epilepsy, parkinsonism.

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.

PRECAUTIONS

Special care and consideration are required when bethanechol is administered to patients being treated concomitantly with other drugs with which pharmacologic interactions may occur. Examples of drugs with potentials for such interactions are: quinidine and procainamide, which may antagonize cholinergic effects; cholinergic drugs, particularly cholinesterase inhibitors, where additive effects may occur. When administered to patients receiving ganglionic blocking compounds a critical fall in blood pressure may occur which usually is preceded by severe abdominal symptoms.

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.

ADVERSE REACTIONS

Abdominal discomfort, salivation, flushing of the skin ("hot feeling"), sweating.

Large doses more commonly result in effects of parasympathetic stimulation, such as malaise, headache, sensation of heat about the face, flushing, colicky pain, diarrhea, nausea and belching, abdominal cramps, borborygmi, asthmatic attacks and fall in blood pressure.

SYMPTOMS AND TREATMENT OF OVERDOSAGE

Symptoms of an overdose are an extension of the adverse effects. In rare instances violent symptoms of cholinergic over stimulation including fall in blood pressure, circulatory collapse, cardiac arrest, shock, severe abdominal cramps with bloody diarrhea and possibly severe bronchospasm may occur.

Atropine is a specific antidote. A syringe containing a dose for adults of 600 µg or more of atropine sulfate should always be available to treat symptoms of toxicity. Use proportionally smaller amounts for children. Subcutaneous injection is preferred except in emergencies; when the i.v. route may be employed. Administer atropine, followed by general supportive and symptomatic treatment.

DOSAGE AND ADMINISTRATION

Must be individualized, depending on the type and severity of the condition to be treated. It is preferable to give the drug when the stomach is empty. If taken soon after eating, nausea and vomiting may occur. The usual adult oral dosage is 10 to 50 mg, 3 to 4 times a day. The minimum effective dose is determined by giving 5 to 10 mg initially and repeating the same amount at hourly intervals until a satisfactory response occurs or a maximum of 50 mg has been given. The effects of the drug appear within 60 to 90 minutes and persist for up to 6 hours. Individual doses should therefore, be spaced at least 6 hours apart.

AVAILABILITY OF DOSAGE FORMS

10 mg: Each pale orange, flat, beveled, round tablet, with "10" debossed on one side and debossed with a Paladin shield on the other, contains: bethanechol chloride 10 mg. Bottles of 100.

25 mg: Each white, flat, beveled, round tablet, with "25" debossed on one side and debossed with a Paladin shield on the other, contains: bethanechol chloride 25 mg. Bottles of 100.

50 mg: Each tan, flat, beveled, round tablet, with "50" debossed on one side and debossed with a Paladin shield on the other, contains: bethanechol chloride 50 mg. Bottles of 100.

Store below 40°C. Keep container tightly closed.