

Uricon[®]

Tablet

Description

Uricon contains Oxybutynin Chloride which is an antispasmodic, anticholinergic agent and formulated as a once a day controlled release tablet for oral administration. Oxybutynin Chloride relaxes bladder smooth muscle. In patients with conditions characterized by involuntary bladder contractions, Oxybutynin Chloride increases bladder capacity, diminishes the frequency of uninhibited contractions of the detrusor muscle, and delays the initial desire to void. Uricon thus decreases urgency and the frequency of both incontinent episodes and voluntary urination.

Indications

Uricon is a once daily controlled release tablet indicated for the treatment of overactive bladder with symptoms of urinary incontinence, urgency for urination, frequent urination and nocturnal enuresis.

Dosage and Administration

Uricon may be administered with or without food. The recommended starting dose of Uricon is 5 mg once daily. Dosage may be adjusted in 5 mg increments to achieve a balance of efficacy and tolerability (up to a maximum of 30 mg/day). In general, dosage adjustment may proceed at approximately weekly intervals.

Contraindication

Oxybutynin is contraindicated in patients with urinary retention, gastric retention, or uncontrolled narrow angle glaucoma and in patients who are at risk for these conditions. Uricon is also contraindicated in patients who have demonstrated hypersensitivity to the drug itself or other components of the product.

Precautions

Uricon should be used with caution in patients with hepatic or renal impairment, clinically significant bladder outflow obstruction because of the risk of urinary retention, gastrointestinal obstructive disorders, conditions such as ulcerative colitis, intestinal atony, and myasthenia gravis, gastro-oesophageal reflux and/or who are concurrently taking drugs (such as bisphosphonates) that can cause or exacerbate oesophagitis.

Drug Interactions

The concomitant use of Oxybutynin with other anticholinergic drugs or with other agents which produce dry mouth, constipation, drowsiness, and/or other anticholinergic-like effects may increase the frequency and/or severity of such effects. Anticholinergic agents may potentially alter the absorption of some concomitantly administered drugs due to anticholinergic effects on gastrointestinal motility.

Pharmacokinetic studies with patients concomitantly receiving cytochrome P450 enzyme inhibitors, such as antimycotic agents (e.g., Ketoconazole, Itraconazole, and Miconazole) or macrolide antibiotics (e.g., Erythromycin and Clarithromycin), have not been performed. No specific drug-drug interaction studies have been performed with Oxybutynin.

Side Effects

The incidence of dry mouth may occur which is dose related. Abdominal pain, dry nasal and sinus mucous membranes, back pain, hypertension, palpitation, vasodilatation, flatulence, gastro-oesophageal reflux, insomnia, nervousness, confusion, cough, sinusitis, bronchitis, dry skin, rash, impaired urination (hesitancy), urinary retention, etc. may be reported.

Use in Special Populations

Pregnancy :The safety of Oxybutynin administration to women who are or who may become pregnant has not been established. Therefore, Oxybutynin should not be given to pregnant women unless, the probable clinical benefits outweigh the possible hazards.

Lactation : It is not known whether Oxybutynin is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Oxybutynin is administered to a nursing woman.

Commercial Pack

Uricon® Tablet : Box containing 30 tablets in 3 x 10's blister strips. Each controlled release tablet contains Oxybutynin Chloride USP 5 mg.