

FLAVOTIDE Tablets (Flavoxate hydrochloride) Composition

FLAVOTIDE-200 Tablet Each tablet contains

Flavoxate hydrochloride 200 mg Dosage Form

Tablet Pharmacology

Pharmacodynamics Mechanism of Action Flavoxate hydrochloride (and its main metabolite methyl flavone carboxylic acid, MFCA) is an antispasmodic selective to the urinary tract. In animal and human studies, flavoxate hydrochloride has been shown to have a direct antispasmodic action on smooth muscle fibres. The mechanism of action involves intracellular cyclic AMP accumulation and calcium blocking activity. It inhibits bladder contractions induced by various agonists or by electrical stimulation and inhibits the frequency of bladder voiding contractions. It increases bladder volume capacity, reduces the threshold and micturition pressure. In addition, animal studies have shown flavoxate hydrochloride to have analgesic and local anaesthetic properties. Flavoxate does not significantly affect cardiac or respiratory functions.

Pharmacokinetics

Oral studies in man have indicated that flavoxate is readily absorbed from the intestine and converted, to a large extent, almost immediately to MFCA. Following an IV dose (equimolar to 100 mg), the following parameters were calculated for flavoxate: $T_{1/2}$ 83.3 mins: apparent volume of distribution 2.89 l/kg. The apparent distribution of MFCA was 0.20 l/kg. No free flavoxate was found in urine (24 hours). However, 47% of the dose was excreted as MFCA. Following single oral dosing to volunteers of 200 mg and 400 mg flavoxate, almost no free flavoxate was detected in the plasma. The peak level of MFCA was attained at 30-60 mins after the 200 mg dose and at around two hours following the 400 mg dose. The AUC for the 400 mg dose was approximately twice as large as the AUC for the 200 mg dose. About 50% of the dose was excreted as MFCA within 12 hours; most being excreted within the first 6 hours. After repeated oral dosing (200 mg, TDS, 7 days) the cumulative excretion of metabolites stabilized at 60% of the dose on the third day remaining almost unchanged after one week.

Indications

FLAVOTIDE is indicated for the symptomatic relief of dysuria, urgency, nocturia, vesical supra-pubic pain, frequency and incontinence as may occur in cystitis, prostatitis, urethritis, urethro-cystitis and urethrotrigonitis. FLAVOTIDE is also indicated for the relief of vesico-urethral spasms due to catheterisation, cystoscopy or indwelling catheters; prior to cystoscopy or catheterisation; sequelae of surgical intervention of the lower urinary tract. Dosage And Administration

For oral Administration Adults (including the elderly) The recommended adult dosage is one tablet three times a day for as long as required. Children FLAVOTIDE tablets are not recommended for children under 12 years of age. Contraindications

The following obstructive conditions: pyloric or duodenal obstruction, obstructive intestinal lesions or ileus, achalasia, gastro-intestinal haemorrhage and obstructive uropathies of the lower urinary tract Hypersensitivity to flavoxate hydrochloride or to any of the excipients of FLAVOTIDE. Warnings And Precautions

General FLAVOTIDE should be used with caution in patients with suspected glaucoma, especially closed angle cases and in patients with serious, uncontrolled, obstructive disorders of the lower urinary tract. Where evidence of urinary infection is present, appropriate anti-infective therapy should be instituted concomitantly. Patients with rare hereditary problems of galactose intolerance, the Lapp lactose deficiency or glucosegalactose malabsorption should not take this medicine. Effects on Ability to Drive and Use Machines The event of drowsiness, blurred vision and vertigo, the patient should not operate a motor vehicle or machinery. Interaction with Other Medicinal Products and Other Forms of Interaction None known. Pregnancy and Lactation Since there is no evidence of the drug's safety in human pregnancy, nor any evidence from animal work that it is free from hazard, FLAVOTIDE should be avoided in pregnancy unless there is no safer alternative. It is not known whether flavoxate is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when FLAVOTIDE is administered during breast-feeding.

Undesirable Effects

In clinical trials comparing flavoxate hydrochloride with other antispasmodic agents, the incidence of sideeffects was low. The following adverse reactions have been observed: Blood and lymphatic disorders: Eosinophilia, leukopenia. Immune system disorders: Hypersensitivity reactions Nervous system disorders: Drowsiness, dizziness, headache, mental confusion (especially in the elderly), nervousness, vertigo. Eye disorders: Blurred vision, disturbances in eye accommodation, increased ocular tension. Cardiac disorders: Palpitations, tachycardia. Gastrointestinal disorders: Diarrhoea, dry mouth, dyspepsia, dysphagia, nausea, vomiting. Skin and subcutaneous tissue disorders: Angioedema, urticaria, erythema, rash, pruritis Renal and urinary disorders: Dysuria. General disorders: Fatigue, hyperpyrexia. Overdosage

No case of overdose has been reported. The signs and symptoms of significant overdosing of FLAVOTIDE are predicted to be similar to those of other anticholinergics. These generally involve the autonomic nerve endings and the brain and include nausea, vomiting, flushing, dilated pupils, dry mouth and

tongue, hot dry skin, fever, sinus tachycardia, hypertension, ataxia, nystagmus, drowsiness, delirium, agitation and visual hallucinations. Uncommonly, systemic features of anticholinergics toxicity include myoclonic jerking, coma, convulsions, cardiac conduction abnormalities and dysrhythmias, cardiovascular collapse, paralytic ileus, urinary retention. Consider activated charcoal if a patient presents within one hour of ingestion of a potentially toxic amount. Alternatively the role of gastric lavage should be considered in adults presenting within 1 hour of a potentially life-threatening overdose. Treatment is supportive and observation for 6 hours after ingestion, without other specific treatment, will be sufficient for the majority of patients. Because strategies for the management of overdose are continually evolving, it is advisable to contact a poison control centre to determine the latest recommendations for the management of an overdose. Storage And Handling Information

Do not store above 30°C. Packaging Information

FLAVOTIDE Tablets.....Alu Alu pack of 10 tablets

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