For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only

FLAVOSPAS TAB

(Flavoxate hydrochloride)

COMPOSITION

Each sugar coated tablet contains:
Flavoxate Hydrochloride I.P. …….. 200 mg
Colour: Titanium Dioxide I.P.

DESCRIPTION

Flavospas tablets contain Flavoxate hydrochloride, a synthetic urinary tract direct spasmolytic. It also has mild analgesic and local anaesthetic effect. Flavoxate hydrochloride counteracts smooth muscle spasm of the urinary tract and exerts its effect directly on the muscle.

CLINICAL PHARMACOLOGY

Pharmacodynamics

Pharmacotherapeutic Group: Urinary antispasmodics – Flavoxate
ATC code: G04BD02
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.

Pharmacokinetic

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: T½ 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 stabilised at 60% of the dose on the third day remaining almost unchanged after one week.

INDICATIONS
Flavoxate 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. In addition, the preparation is 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.

CONTRAINDICATION
The following obstructive conditions: pyloric or duodenal obstruction, obstructive intestinal lesions or ileus, achalasia, gastrointestinal haemorrhage and obstructive uropathies of the lower urinary tract.

Hypersensitivity to flavoxate hydrochloride or to any of the excipients of Flavoxate 200.

WARNINGS AND PRECAUTIONS
Flavoxate 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.

DRUG INTERACTION
None known.

ADVERSE EFECTS
In reported clinical trials comparing Flavoxate with other antispasmodic agents, the incidence of side-effects was low. The following adverse reactions have been reported:
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 Flavoxate 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.

DOSAGES 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:

Flavoxate tablets are not recommended for children under 12 years of age.

USE IN PREGNANCY AND NURSING MOTHER
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, Flavoxate 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 Flavoxate is administered during breast-feeding.

EXPIRY DATE
Three years from the date of manufacturing.

STORAGE
Store in a cool, dry place. Protect from light

PRESENTATION
Blister pack of 10 Tablets

MARKETED BY


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