For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory xxxxxxxx-8883

TOPCID

Famotidine Tablets U.S.P. (20 mg & 40 mg)

DESCRIPTION:

Topcid (famotidine) is a histamine H_2-receptor antagonist which is indicated in the short term treatment of active duodenal ulcer, benign gastric ulcer, maintenance therapy of duodenal ulcer and benign gastric ulcer and in hypersecretory states such as Zollinger-Ellison Syndrome.

CLINICAL PHARMACOLOGY:

Topcid is a competitive inhibitor of histamine H_2-receptors. Both the acid concentration and volume of gastric secretion are suppressed by Topcid, while changes in pepsin secretion are proportional to volume output. In both, normal volunteers and hypersecretors, Topcid inhibited both basal and nocturnal gastric secretion, as well as secretion stimulated by food and pentagastrin. After oral administration of Topcid, the onset of the antisecretory effect occurred within one hour; the maximum effect was dose-dependent and occurred within 1-3 hours. The duration of inhibition of acid secretion by Topcid was 10-12 hours.

Topcid is incompletely absorbed. The bioavailability of oral doses is 40-45%. Topcid undergoes slight first-pass metabolism. The elimination half-life of Topcid is 2.5 - 3.5 hours. The half-life of Topcid is related to creatinine clearance values and in patient with severe renal insufficiency (creatinine clearance less than 10mL/minute), the elimination half-life of Topcid may exceed 20 hours and adjustment of dose or dosing intervals may be necessary.

INDICATIONS:

1. Topcid is indicated for short term treatment of active duodenal ulcer and benign gastric ulcer. Most patients heal within 4 weeks and there is rarely any reason to use Topcid at full dosage for longer than 6-8 weeks.
2. Topcid has been used for maintenance therapy for duodenal ulcer and benign gastric ulcer patients at reduced dosage after healing of an active ulcer, upto one year.
3. Topcid has also been used in treatment of pathological hypersecretory conditions (e.g. Zollinger-Ellison Syndrome, Zollinger-Ellison Syndrome, multiple endocrine adenomas).

CONTRAINDICATIONS:

Topcid is contraindicated in patients who are hypersensitive to any component of the tablet.

PRECAUTIONS:

Gastric malignancy should be excluded prior to initiation of therapy of gastric ulcer with Topcid. Symptomatic response of gastric ulcer to therapy does not preclude the presence of gastric malignancy.

Since Famotidine is excreted via kidney, caution should be exercised when treating patients with impaired renal function.

USE IN PREGNANCY, LACTATION AND CHILDREN:

Topcid is not recommended for use in pregnancy and should be prescribed only if clearly needed.

Topcid is secreted into human milk, therefore nursing mothers should either stop breast-feeding or stop taking the drug.

The efficacy and safety of use of Topcid in children has not been established.

ADVERSE REACTIONS:

'Famotidine has been demonstrated to be generally well-tolerated.

[Very Common (>1/10) Common (>1/100, <1/10) Uncommon (>1/1000, <1/100) Rare (>1/10,000, <1/1,000) Very rare (<1/10,000) including isolated cases Not known (cannot be estimated from the available data)]

Nervous system disorders:
Common: headache, dizziness
Uncommon: taste disorder
Very rare: convulsions, grand mal seizures (particularly in patients with impaired renal function), paraesthesia, somnolence
Respiratory, thoracic, and mediastinal disorders:
Very rare: interstitial pneumonia sometimes fatal
Gastro-intestinal disorders:
Common: constipation, diarrhoea
Uncommon: dry mouth, nausea and/or vomiting, abdominal discomfort of distension, flatulence
Metabolism and nutrition disorders:
Uncommon: anorexia
Hepatobiliary disorders:
Very rare: liver enzyme abnormalities, hepatitis, cholestatic jaundice
Skin and subcutaneous tissue disorders:
Uncommon: rash, pruritus, urticaria

Very rare: alopecia, Stevens Johnson Syndrome/toxic epidermal necrolysis sometimes fatal
Immune system disorders:
Very rare: hypersensitivity reactions (anaphylaxis, angioneurotic oedema, bronchospasm)
Musculoskeletal and connective tissue disorders:
Very rare: arthralgia, muscle cramps
General disorders and administration site conditions:
Uncommon: fatigue
Very rare: chest tightness
Psychiatric disorders:
Very rare: reversible psychic disturbances including depression, anxiety disorders, agitation, disorientation, confusion and hallucinations, reduced libido, insomnia
Blood and lymphatic disorders:
Very rare: pancytopenia, leucopenia, thrombocytopenia, agranulocytosis, neutropenia.
Reproductive system and breast disorders:
Very rare: impotence
Cardiac disorders:
Very rare: A-V block with H_2 receptor antagonists administered intravenously.
Adverse Effects – Causal Relationship Unknown

Rare cases of gynaecomastia have been reported, however, in controlled clinical trials the incidences were not greater than those seen with placebo.

DRUG INTERACTIONS:

No drug interactions of clinical importance have been identified.

Famotidine does not interact with the cytochrome P450-linked drug metabolising enzyme system. Compounds metabolised by this system which have been tested in man have included warfarin, theophylline, phenytoin, diazepam, propranolol, aminopyrine and antipyrine. Indocyanine green as an index of hepatic blood flow and/or hepatic drug extraction has been tested and no significant effects have been found.

Studies in patients stabilised on phenprocoumon therapy have shown no pharmacokinetic interaction with famotidine and no effect on the pharmacokinetic or anticoagulant activity of phenprocoumon.

In addition, studies with famotidine have shown no augmentation of expected blood alcohol levels resulting from alcohol ingestion.

Alterations of gastric pH may affect the bioavailability of certain drugs resulting in a decrease in the absorption of atazanavir.

The absorption of ketoconazole and itraconazole could be reduced. Ketoconazole should be given 2 hours before famotidine administration.

Antacids may decrease the absorption of famotidine and lead to lower plasma concentrations of famotidine. Famotidine should therefore be taken 1 - 2 hours before the application of an antacid.

The administration of probenecid can delay the elimination of famotidine. Concomitant use of probenecid and famotidine should be avoided.

The concomitant use of sucralfate should be avoided within two hours of the famotidine dose.

DOSAGE AND ADMINISTRATION:

Acute Therapy : The recommended adult oral dosage for active duodenal ulcer and benign gastric ulcer is 40mg once a day at bedtime. Most patients heal within 4 weeks. The regimen of 20 mg twice a day is also equally effective.

Maintenance Therapy : The recommended oral dose is 20 mg once a day at bedtime.

Pathological Hypersecretory Conditions : This vary with individual patient. The recommended adult oral starting dose is 20mg every 6 hours. Doses upto 160mg every 6 hours have been administered to some patients with severe Zollinger-Ellison Syndrome.

In patients with severe renal insufficiency, the daily dose is recommended as 20 mg at bedtime or 40mg should be administered at intervals of 36-48 hours.

OVERDOSAGE

Doses up to 640 mg/day have been given to patients with pathological hypersecretory conditions with no serious adverse effect. In the event of overdosage, treatment should be symptomatic and supportive.

PRESENTATION

Topcid is available as film coated tablet in strip of 10; each tablet contain famotidine 20 mg or 40 mg.

torrent

Manufactured by :
TORRENT PHARMACEUTICALS LTD.
Vill. Bhud & Makhnu Majra, Baddi-173 205,
Teh. Nalagarh, Dist. Solan (H.P.), INDIA.