TOPCID

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

Abbreviated Prescribing information for TOPCID tablets [Famotidine 20mg and 40mg] [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Famotidine is a competitive inhibitor of histamine H₂-receptors and primarily inhibit gastric secretion. Both the acid concentration and volume of gastric secretion are suppressed, while changes in pepsin secretion are proportional to volume output.

INDICATIONS: Indicated in the treatment of duodenal ulcer, peptic ulcer, pathological hypersecretory disorders e.g. Zollinger Ellison Syndrome.

DOSAGE AND ADMINISTRATION: Duodenal Ulcer: Acute Therapy- 40 mg once a day at bedtime. Maintenance Therapy- 20 mg once a day at bedtime. Benign Gastric Ulcer: Acute therapy- 40 mg once a day at bedtime. Dosage for Pediatric Patients 1-16 years of age: Peptic ulcer - 0.5 mg/kg/day p.o. at bedtime or divided b.i.d. up to 40 mg/day (treatment duration initially based on adult duration recommendations and dose should be individualized based on clinical response and/or gastric or esophageal pH determination and endoscopy). Pathological hypersecretory conditions (e.g. Zollinger Ellison syndrome): starting dose-20mg at every 6 h. Doses up to 160 mg at every 6 h have been administered to some adult patients with severe condition. Moderate and severe renal insufficiency: reduce the dose to half and prolong dosing interval up to 36-48 hours.

CONTRAINDICATION: Hypersensitivity to any component of these product or patients with a history of hypersensitivity to other H₂-receptor antagonists.

WARNINGS & PRECAUTIONS: Symptomatic response to therapy with famotidine does not preclude the presence of gastric malignancy. Risk of CNS adverse effects in patients with moderate or severe renal insufficiency.

ADVERSE REACTIONS: headache, dizziness, constipation, diarrhea, fever, asthenia, fatigue, arrhythmia, AV block, palpitation, cholestatic jaundice, hepatitis, liver enzyme abnormalities, vomiting, nausea, abdominal discomfort, anorexia, dry mouth, agranulocytosis, pancytopenia, leukopenia, thrombocytopenia, anaphylaxis, angioedema, orbital or facial edema, urticaria, rash, conjunctival injection, musculoskeletal pain including muscle cramps, arthralgia, grand mal seizure, psychic disturbances including hallucinations, confusion, agitation, depression, anxiety and decreased libido, paresthesia, insomnia, somnolence, Convulsions, in patients with impaired renal function, bronchospasm, interstitial pneumonia, toxic epidermal necrolysis/Stevens-Johnson syndrome, alopecia, acne, pruritus, dry skin, flushing, tinnitus, taste disorder and gynecomastia.

MARKETED BY:



TORRENT PHARMACEUTICALS LTD. Torrent House, Off Ashram Road, Ahmedabad-380 009, INDIA

IN/ TOPCID /20mg,40mg/Mar-2015/01/AbPI

(Additional information is available on request)