

# Temtac<sup>®</sup>

Famotidine

## COMPOSITION:

Temtac<sup>®</sup> 20 Tablet: Each film coated tablet contains Famotidine USP 20mg.

Temtac<sup>®</sup> PFS: After reconstitution each 5ml suspension contains Famotidine USP 40mg.

## PHARMACOLOGY:

Famotidine is a Histamine H2 receptor antagonist that inhibits the secretion of gastric acid by working on H2 receptors of parietal cells. The H2 receptor blocker activity of famotidine is slowly reversible because Famotidine shows high selectivity towards H2 receptors.

## INDICATION:

Famotidine is indicated for the management of duodenal ulcer, gastric ulcer, gastro esophageal reflux disease, acute stress ulcer & Zollinger Ellison syndrome. Famotidine is also indicated for the treatment of acute and chronic gastritis.

## DOSE & ADMINISTRATION:

### Tablet:

• **For gastric ulcer, duodenal ulcer, gastric ulcer, gastro esophageal reflux disease, acute stress ulcer & Zollinger Ellison syndrome:** Usual dose for adults: Famotidine 20 mg twice daily (after breakfast and after supper or before bed time) or Famotidine 40 mg can be administered orally once daily at bed time. Most ulcer patients heal within 4-8 weeks.

**Maintenance therapy:** The recommended oral dose is 20 mg once daily. Or, as directed by the registered physician.

### Powder for Suspension:

Gastroesophageal Reflux Disease(GERD):

- <1 year of age: 0.5 mg/kg/dose of famotidine oral suspension up to 8 weeks once daily in patients
- Age 3 to 11 months: 0.5 mg/kg/dose twice daily up to 8 weeks
- Age 1 to 2 months: 0.5 mg/kg/dose once daily up to 8 weeks
- Neonates: 0.5 mg/kg/dose maximum once daily up to 8 weeks

Patients 1-16 years of age:

- Gastroesophageal Reflux Disease (GERD): 1 mg/kg/day p.o. divided b.i.d. up to 40 mg b.i.d.
- Duodenal ulcer: 0.5 mg/kg/day p.o. at bedtime or divided b.i.d. up to 40 mg/day.
- Peptic ulcer: 0.5 mg/kg/day p.o. at bedtime or divided b.i.d. up to 40 mg/day.
- Maintenance therapy: 40 mg at daily night.
- Reflux esophagitis: 2 mg/kg/day
- Zollinger-Ellison Syndrome: 40 mg 3 times daily.

## CONTRA-INDICATION:

Famotidine is contraindicated to patients known to have hypersensitivity to the drug or any of the ingredients.

## WARNING AND PRECAUTION:

CNS adverse effects have been reported in patients with moderate and severe renal insufficiency, longer intervals between doses or lower doses may need to be used in patients with moderate creatinine clearance.

## SIDE EFFECTS:

Side effects of famotidine are generally rare and infrequent but administration of Famotidine can cause rash constipation, diarrhea, dry mouth, nausea, vomiting, headache, drowsiness & abdominal discomfort.

## USE IN PREGNANCY & LACTATION:

Pregnancy category B. There are no adequate and well-controlled studies in pregnant women. This drug should be used during pregnancy only if clearly needed. Caution should be exercised when Famotidine administered to a nursing woman.

## USE IN CHILDREN & ADOLESCENTS:

Famotidine can be used patients of below three months of age.

## DRUG INTERACTION:

No clinically important drug interaction have been identified. Famotidine does not interact with the cytochrome P450 linked drug metabolizing enzyme system.

## OVERDOSE:

Overdose can cause abdominal discomfort, diarrhea, dry mouth, nausea & vomiting.

## STORAGE:

Store in a dry and cool place below 30° C temperature and keep away from light and moisture. Keep out of reach of children.

## PACKING:

Temtac<sup>®</sup> 20 Tablet: Each box contains 10 X 10's film coated tablets in Alu-Alu blister pack.

Temtac<sup>®</sup> PFS: Each bottle contains 50 ml powder for suspension with a measuring cup and dropper.



Manufactured by

**Team Pharmaceuticals Ltd.**

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