

# PACKAGE INSERT

## SUNPEPCIN 20 / 40 TABLET

Each tablet contains:	<b>Sunpepcin 20 Tablet</b> Famotidine 20mg	<b>Sunpepcin 40 Tablet</b> Famotidine 40mg
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**Product Description:**  
Sunpepcin 20 Tablet: Oval, beige, convex, film-coated tablet with single score on one side only.  
Sunpepcin 40 Tablet: Oval, brown, convex, film-coated tablet with single score on one side only.

**Pharmacodynamics:**  
Famotidine is a competitive inhibitor of histamine H<sub>2</sub> receptors. It inhibits gastric secretion, that is both the acid concentration and volume of basal and stimulated gastric secretion suppresses, while changes in pepsin secretion are proportional to volume output. Famotidine had little or no effect on fasting or postprandial serum gastrin levels. Gastric emptying and exocrine pancreatic function were not affected by famotidine.

**Pharmacokinetics:**  
Famotidine is incompletely absorbed. The bioavailability of oral doses is 40-45% and is not significantly affected by the presence of food. Famotidine undergoes minimal first-pass metabolism. After oral doses, peak plasma levels occur in 1-3 hours. Plasma level after multiple doses are similar to those after single doses. 15 to 20% of famotidine in plasma is protein bound. Famotidine has an elimination half-life of 2.5-3.5 hours and is prolonged in renal impairment. Famotidine is eliminated by renal (65-70%) and metabolic (30-35%) routes. 25 - 30% of an oral dose is recovered in the urine as unchanged compound. The only metabolite identified in man is the S-oxide.

**Indication:**  
a) Treatment of active duodenal ulcer  
b) Treatment of active benign gastric ulcer  
c) Maintenance therapy for duodenal ulcer  
d) Short term treatment for symptomatic relief of gastroesophageal reflux disease  
e) Treatment of pathological hypersecretory conditions (eg. Zollinger-Ellison syndrome, multiple endocrine adenomas).

**Recommended Dosage:**  
For adults 18 years and older.  
**Duodenal and gastric ulcer:**  
The recommended dose is 40mg daily at bedtime for 4-8 weeks. A regimen of 20mg twice daily is also effective. In most cases of duodenal ulcer, healing occur within 4 weeks on this regimen. In those patients whose ulcers have not healed after 4 weeks, treatment should be continued for a further 4 weeks period.  
Maintenance therapy: 20mg daily at bedtime may be given to prevent the recurrence of duodenal ulcers.

**Gastro Esophageal Reflux Disease (GERD):**  
Recommended dosage for the symptomatic relief is 20mg bid for 6 weeks. For the treatment of patients with esophagitis including erosions and ulcerations and accompanying symptoms due to GERD is 20 to 40mg bid for up to 12 weeks.

**Pathological Hypersecretory Conditions (e.g. Zollinger - Ellison Syndrome, Multiple Endocrine Adenomas)**  
The recommended dose is 20mg every 6 hours, increased as necessary. Doses should be adjusted to individual patients needs and should continue as long as clinically indicated. Some patients have been maintained on 800mg daily.

**Renal Insufficiency:**  
Dosage adjustment is required for patients with moderate to severe renal insufficiency. In patients with severe renal insufficiency, i.e. with a creatinine clearance less than 10ml/min, the elimination half-life of famotidine may exceed 20 hours, reaching approximately 24 hours in anuric patients. Since CNS adverse effects have been reported in patients with moderate to severe renal insufficiency, to avoid excess accumulation of the drug, the dose of famotidine may be reduced to half the recommended dose or the dosing interval may be prolonged to 36 to 48 hours as indicated by the patient's clinical response.

**Route of Administration:** Oral

**Contraindications:**  
Contraindicated in patients who exhibit hypersensitivity to any components of this product and in patients with a history of hypersensitivity to other H<sub>2</sub> receptor antagonists.

**Warnings and Precautions:**  
**General:**  
Gastric malignancy should be excluded prior to initiation of therapy with famotidine. Symptomatic responses to therapy with famotidine does not preclude the presence of gastric malignancy.

**Renal Insufficiency:**  
Longer intervals between doses or lower doses may need to be used in patients with severe renal insufficiency (creatinine clearance lower than 10ml/min) to adjust for the longer elimination half-life of famotidine.

**Use in children:**  
Safety and effectiveness in children have not been established.

**Use in elderly:**  
As elderly patients are more likely to have decreased clearance of famotidine care should be taken in dose selection and it may be useful to monitor renal function. Dosage adjustment in the case of severe renal impairment may be necessary.

**Interactions with Other Medicaments:**  
Concurrent administration of famotidine and antacid may result in a decrease in the bioavailability of famotidine, but the interaction could be minimised by separating ingestion by 2 hours. Probenecid has been reported to inhibit renal tubular secretion of famotidine. Hence, the maximum serum concentration of famotidine and the area under the concentration / time curve were significantly increased.

**Pregnancy And Lactation:**  
There are no adequate or well-controlled studies in pregnant women and this drug should be used during pregnancy only if clearly needed. Famotidine should not be used during pregnancy unless the potential benefits outweigh the potential risks to the foetus. Famotidine is detectable in human milk. Hence, a decision should be made whether to discontinue nursing or discontinue the drug.

**Side Effects:**  
Famotidine is generally well-tolerated with side-effects such as headache, dizziness, constipation and diarrhea reported rarely.

Other side effects which are reported infrequently includes:  
Gastrointestinal : Nausea, cholestatic jaundice, liver enzyme abnormalities, vomiting, abdominal discomfort, anorexia, dry mouth.  
Hematologic : Leukopenia, agranulocytosis, thrombocytopenia, pancytopenia.  
Cardiovascular : Palpitation.  
Hypersensitivity : Anaphylaxis, angioedema, orbital or facial oedema, urticaria, rash.  
Musculoskeletal : Musculoskeletal pain, arthralgia.  
Nervous system : Grand mal seizure, hallucinations, confusion, agitation, depression, anxiety, decreased libido, paresthesia, insomnia, somnolence.  
Respiratory : Bronchospasm.  
Skin : Alopecia, acne, pruritus, dry skin, flushing, toxic epidermal necrolysis (very rare).  
Miscellaneous : Fever, asthenia and fatigue.

**Symptoms and Treatment of Overdose:**  
There is no experience to date with deliberate overdosage. Oral doses of up to 800mg/day have been given to patients with pathological hypersecretory conditions with no serious adverse effects. In the event of overdosage, treatment should be symptomatic and supportive. Unabsorbed material should be removed from the gastrointestinal tract, the patient should be monitored, and supportive therapy should be employed.

**Effects on Ability to Drive and Use Machine:** Not applicable.

**Storage Conditions:**  
Store at or below 30°C.

**Pack Sizes:** Blister pack: A box of 10 x 10, 50 x 10 and 100 x 10 tablets per strip.  
**Pack Size (export only):** A bottle of 500 tablets.

**Shelf-life:** 3 years.

**FURTHER INFORMATION CONCERNING THIS DRUG CAN BE OBTAINED FROM YOUR FAMILY PHYSICIAN / LOCAL GENERAL PRACTITIONER / PHARMACIST.**

Manufacturer & Product Registration Holder:  
SUNWARD PHARMACEUTICAL SDN. BHD.  
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