SUNPEPCIN TABLET®

Famotidine (20mg, 40mg)

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What Sunpepcin Tablet is used for

- Treatment of active duodenal ulcer.
- Treatment of active benign gastric ulcer.
- Maintenance therapy of duodenal ulcer
- Short-term treatment to relieve gastroesophageal reflux symptoms caused by the backflow of stomach acid into the esophagus channels.
- Treatment of Pathological Hypersecretory condition where the body produces excess stomach acid. For example Zollinger-Ellison syndrome (tumor cells in the pancreas causes excess production of gastric acid) and Multiple Endocrine adenomas (tumors of the endocrine glands)

How Sunpepcin Tablet Works

The active ingredient in the medicine is famotidine. Famotidine belongs to a group of medicines called H2 antagonists or H2 blockers. It works by reducing the amount of acid made by the stomach. This helps to reduce the pain and also allows the ulcer and/or reflux disease to heal.

Before you use Sunpepcin Tablet

- When you must not use it

• If you have exhibited hypersensitivity to this product or other similar medicines.

-Before you start to use it

You should check with your doctor:-

- If you have renal insufficience.
- If you are pregnant or breastfeeding. Famotidine should not be used during pregnancy unless the potential benefits outweigh the potential risks to the fetus. Famotidine is detectable in human milk. Hence, a decision should be made whether to discontinue nursing or discontinue the medicine.
- The doctor may arrange additional tests to diagnose stomach cancer before starting Sunpepcin tablet because famotidine can mask the symptoms and delay the diagnosis.

- Taking Other Medicines

Some medicines and Sunpepcin tablet may interfere with each other. In particular, tell your doctor or pharmacist if you are taking any of the following medicines listed below:

- Medicines that relieve heartburn such as antacids
- Medicines that treat gout such as probenecid.

How to use Sunpepcin Tablet

- How much to use

Oral administration.

For adults 18 years and above,

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.

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 twice daily for 6 weeks. For the treatment of people with esophagus inflammation including erosions and ulcerations and accompanying symptoms due to GERD is 20 to 40mg twice daily 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 needs. Some people have been maintained on 800mg daily.

Kidney insufficiency: Dosage adjustment is required for people with moderate to severe kidney insufficiency. Since adverse effects have been reported in people with kidney insufficiency, to avoid excess accumulation of the medicine, the dose of famotidine may be reduced to half the recommended dose or the dosing interval may be prolonged to 36 to 48 hours according to the person response.

- When to use it

Refer to your doctor or pharmacist.

- How long to use it

It is important to take Sunpepcin tablet as long as your doctor prescribes.

- If you forget to take it

Do not take extra dose to make up for a missed dose. Just take your next dose at usual time.

-If you use too much (overdose)

If you take too much of the medication by mistake, contact your doctor immediately or seek medical attention.

While you are using it

- Things you must do

Take Sunpepcin Tablet exactly the way as prescribed.

- Things you must not do

Do not share your medicines with others even if they have the same problem as you.

- Things to be careful of

If you experience any side effects, consult your doctor or pharmacist for advice.

Side Effects

Side effects of Famotidine are like headache, dizziness, constipation and diarrhea which have been reported rarely other rare side effects reported include:-

Gastrointestinal:

nausea, jaundice, liver enzyme abnormalities, vomiting, discomfort in the abdomen, eating disorders, dry mouth.

Hematology: Low white blood cells, low red blood cells and low platelets.

Cardiovascular: palpitation.

Hypersensitivity: Severe allergic reactions, swelling of the skin, eyes or face, hives

Musculoskeletal: muscle, bone or joint pain

Nervous system: seizures, hallucinations, confusion, anxiety, depression, anxiety, decreased in sex drive, abnormal sensation such as numbness, tingling, sleepiness

Respiratory system: Tightening of airway into the lungs.

Skin: Hair loss, acne, itchiness, dry skin, flushing, very rare severe skin reactions like blistering and skin peeling which can be life threatening (toxic epidermal necrosis).

Miscellaneous: Fever, weakness and fatigue.

You may report any side effect or adverse drug reaction directly to the National Centre for Adverse Drug Reaction Monitoring by calling 03-78835550, or visiting the website portal.bpfk.gov.my(Consumers→Reporting)

Storage and Disposal of Sunpepcin Cream

- Storage

Store at temperature 25°C.

- Disposal

If you have any unwanted medicines, do not put them in waste water or household rubbish. Ask your pharmacist how to dispose of the medicine. These steps will help to protect the environment.

Product Description

- What it looks like

MAL20002517A

Oval, beige, convex, film-coated tablet with single score on one side only.

• MAL20002518A

Oval, brown, convex, film-coated tablet with single score on one side only.

- Ingredients

- Active Ingredients
- Famotidine
- Inactive Ingredients
- Microcrystalline Cellulose
- Sodium Starch Glycolate
- Pregelatinized Starch
- Magnesium Stearate
- Hydroxypropyl Methylcellulose
- Deionised Water
- Cellosolve Solvent (M.E)
- Titanium Dioxide
- Calcium Carbonate (light)
- Corn Starch
- Talcum
- Cochineal Red Lake
- Lake Green
- Isopropyl Alcohol (IPA)

<u>- MAL number</u>

- MAL20002517A Famotidine (20mg)
- MAL20002518A Famotidine (40mg)

Manufacturer

Sunward Pharmaceutical Sdn. Bhd. 9,11 & 17 Jalan Kempas 4, Taman Perindustrian Tampoi Indah, 81200 Johor Bahru, Johor, Malaysia.

Product Registration Holder

Sunward Pharmaceutical Sdn. Bhd. 9,11 & 17 Jalan Kempas 4, Taman Perindustrian Tampoi Indah, 81200 Johor Bahru, Johor, Malaysia.

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