

Approval Date: February 20th, 2013
Revision Date: December 15th, 2016

Package Insert of Famotidine Chewable tablets

Please read the package insert carefully and use according to doctor's instructions.

[Drug Name]

Generic Name: Famotidine, Calcium Carbonate and Magnesium Hydroxide Chewable tablets

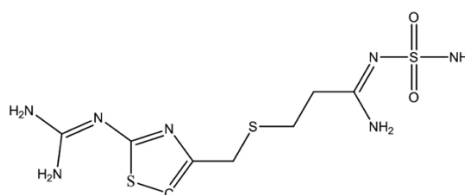
Chinese Pinyin: Famotiding GaiMei Jujue Pian

[Ingredients]

Active ingredients (in each chewable tablet)

Purposes

Famotidine 10 mg



Acid reducer

Calcium carbonate 800 mg

Antacid

Magnesium hydroxide 165 mg

Antacid

[Inactive ingredients]

Ethyl cellulose, Povidone, Microcrystalline cellulose, Aspartame, Mannitol, Lactose, Orange flavoring agent, Peppermint flavoring agent, Magnesium stearate, Ponceau 4R, Allura red, alcohol, water

[Properties]

This product is a pink or pinkish tablets.

[Use]

OTC drug for antacid.

[Indication]

Relieve symptoms including heartburn, stomach pain, chest pain caused by excessive gastric acid secretion.

[Dosage and Administration]

adults and children 12 years and over:

do not swallow tablet whole: chew completely

to relieve symptoms, chew 1 tablet before swallowing

do not use more than 2 chewable tablets in 24 hours
children under 12 years: ask a doctor

[Adverse Reactions]

Patients might experience headache, dizziness, insomnia, constipation and diarrhea; Sometimes rash, urticaria; Rare loss of appetite, leukopenia, AST/ALT elevation, tachycardia, flush and abnormal menstruation.

[Contraindications]

Do not use if: Allergic to this product.
Difficult to swallow
Severe liver or renal function impairment.

[Precautions]

1. Do not use this product more than consecutive 7 days, consult a doctor for further examination if stomach pain do not relieve.
2. Liver-impaired patients should use this product carefully.
3. This product's main ingredient, Famotidine, is excreted through renal, renal-impaired patient should use carefully.
4. Children age under 12 years old should use under doctor's instruction.
5. Pregnant and lactating women should use under doctor's instruction.
6. Do not use with other antacid agents or acid inhibitors.
7. Do not use more than 2 tablets in 24 hours.
8. Except for liver and/or renal impairment elderly patients, NO dose adjustment should be done for elderly patients.
9. Consult a doctor immediately if encounter suddenly unexpected nausea, vomiting, upper abdominal pain.
10. Patients with medical history of central nervous system and neurological disease should use under doctor's instruction.
11. If skin rash occurs after the administration of this product, discontinue the drug immediately.
12. Consult a doctor immediately if over dosage or unexpected adverse reaction occurs.
13. Patients with allergic to this product should use carefully.
14. Do not use if the property of this product changes.
15. Keep out of children's touch.
16. Children should use this product under adult's supervision.
17. If patients under other current medication, consult a pharmacist or doctor before using this product.

[Drug Interactions]

Famotidine do not inhibit liver metabolism enzyme and do not have significant interaction with other drugs. This product have mild interaction with theophylline, phenytoin, warfarin, nifedipine and diazepam, do not effect the distribution of procaine in vivo.

[Pharmacology]

This product contains Famotidine, Calcium carbonate, Magnesium hydroxide. Famotidine is a H2-blocker, which inhibits gastric acid, pepsin secretion, reduce the production of gastric acid. Calcium carbonate and Magnesium hydroxide are antacids which can neutralize gastric acid. With three active ingredients, this product can relieve the symptom of heartburn.

[Storage]

Seal and store under 30°C, and keep away from direct sunlight.

[Packaging]

Aluminum-paper single tablet packaging, 6 tablets/carton
Aluminum-paper single tablet packaging, 8 tablets/carton
Aluminum-paper single tablet packaging, 10 tablets/carton

Aluminum-paper single tablet packaging, 12 tablets/carton
Aluminum-paper single tablet packaging, 16 tablets/carton
Aluminum-paper single tablet packaging, 24 tablets/carton
High density polyethylene bottle, 12 tablets/bottle
High density polyethylene bottle, 30 tablets/bottle

[Shelf-Life]

24 months

[Executive Standard]

National Medical Products Agency standard WS₁-XG-016-2016

[Approval Number]

Guo Yao Zhun Zi H20080048

[Manufacturer]

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