

INFORMATION FOR THE PATIENT

PrFAMOTIDINE

Full prescribing information is available to the physician and pharmacist.

FAMOTIDINE (20 mg and 40 mg tablets) is available **only on prescription** from your physician. Famotidine belongs to a class of medicines known as histamine H₂-receptor antagonists. It reduces the amount of acid produced by the stomach. For this reason it is used in the treatment of certain ulcers of the stomach or duodenum, and other conditions, for example the treatment of gastroesophageal reflux disease or Zollinger-Ellison syndrome, in which the stomach produces too much acid.

Remember—This medicine is prescribed for the particular condition that you have.

Do not give this medicine to other people, nor use it for any other condition.

Do not use outdated medicine.

Keep out of the reach and sight of children.

Read the following information carefully. **If you need any explanations, or further information, ask your physician or pharmacist.**

Before Taking this Medicine: This medicine may not be suitable for some patients. So, tell your physician if you think **any** of the following applies to you:

- Do not take FAMOTIDINE if you are allergic to any of its ingredients or to other H₂-receptor antagonists.
- You are pregnant or intend to become pregnant.
- You are breast-feeding or intend to breast-feed.
- You have confirmed kidney or liver ailment.

- Your physician also needs to know if you are taking any other medication (example, a prescription or over the counter drugs).

Proper Use of this Medicine:

- Take this medicine **exactly** as directed by your physician. For the treatment of ulcers, it is often recommended as a single dose at bedtime; but some conditions may require different dosing. In any case, follow the instructions provided by your physician and your pharmacist.
- If necessary, your physician may also recommend an antacid.
- If you miss the usual time for a tablet, take it as soon as possible. But, if it is too close to the time of your next dose, take only the prescribed dose at the appointed time. **Do not take a double dose.**
- **The safety of famotidine in children has not been established.**
- Carefully follow any dietary measures that your physician has recommended. Certain foods and drinks and certain medicines, such as acetylsalicylic acid, may irritate the stomach and worsen your condition.
- Take this medicine for the full duration of treatment, even if you begin to feel better. The pain usually subsides before complete healing is obtained. **Do not alter the dosage or stop taking the medicine without consulting your physician.**
- FAMOTIDINE does not usually interfere with other medicines that you may be taking. It is important, however, to tell your physician about all the drugs that you are taking, including those obtained without a prescription.
- Store at 15°C to 30°C in a tightly closed container. Protect from light.
- Store unit dose strips at 15°C to 25°C. Protect from light.

Can I drive or operate machinery while using FAMOTIDINE?

There have been side effects such as dizziness reported with famotidine that may affect your ability to drive or operate machinery. Individual responses to famotidine may vary. **Determine your response to famotidine before driving or operating machinery.** (See **SIDE EFFECTS OF THIS MEDICINE - AND WHAT YOU SHOULD DO**).

Overdose:

If you think you, or a person you are caring for, have taken too much FAMOTIDINE, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Side Effects of this Medicine - and What you Should Do:

Along with its intended action, any medication may cause unwanted effects. Most people do not have any problem when taking this medicine.

Check with your physician as soon as possible if any of the following side effects occur: headache, dizziness, diarrhea, constipation and liver problems with symptoms such as abdominal pain, vomiting, fatigue (or tiredness) and jaundice (yellowing of the eyes and skin).

Other side effects reported less frequently are dry mouth, nausea and/or vomiting, stomach discomfort, loss of appetite, tiredness, rash, itching, hair loss, jaundice, painful joints, muscle cramps, and mental disturbances that stopped when the medicine was discontinued. Patients with kidney problems have experienced seizures very rarely.

A few people may be allergic to some medicines. If any of the following side effects occur after taking FAMOTIDINE, stop taking this medicine and contact your doctor immediately: swelling of the face, lips, tongue and/or throat (with difficulty in breathing or swallowing); hives; or severe skin reactions (very rare reports with this class of medicines).

Other effects not listed above may also occur in some patients. If you notice any other unusual symptoms, check with your physician.

Ingredients: Active Ingredient: Each tablet of FAMOTIDINE contains famotidine. It comes in two strengths: 20 mg (buff), and 40 mg (light brown).

Nonmedicinal ingredients: colloidal silicon dioxide, pregelatinized starch, microcrystalline cellulose, magnesium stearate and film coating: titanium dioxide, hydroxypropyl methylcellulose, polyethylene glycol, polysorbate , iron oxide yellow, iron oxide red.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

If you want more information about FAMOTIDINE:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.sivem.ca, or by contacting Sivem Pharmaceuticals ULC by:
Phone: 1 855-788-3153;

This leaflet was prepared by:
Sivem Pharmaceuticals ULC
4705 Dobrin Street
Saint-Laurent, Quebec, Canada
H4R 2P7
www.sivem.ca

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