

Medication Guide
Ibuprofen (eye" bue proe' fen) and Famotidine (fa moe' ti deen)
Tablets, for oral use

What is the most important information I should know about ibuprofen and famotidine tablets?

Ibuprofen and famotidine tablets can cause serious side effects including:

- **Increased risk of a heart attack or stroke that can lead to death.** This risk may happen early in treatment and may increase:
 - o with increasing doses of medicine containing NSAIDs
 - o with longer use of medicine containing NSAIDs

Do not take Ibuprofen and famotidine tablets right before or after a heart surgery called a “coronary artery bypass graft (CABG).” Avoid taking Ibuprofen and famotidine tablets after a recent heart attack, unless your healthcare provider tells you to. You may have an increased risk of another heart attack if you take Ibuprofen and famotidine tablets after a recent heart attack.

- **Increased risk of bleeding, ulcers and tears (perforation) of the esophagus (tube leading from the mouth to the stomach), stomach and intestines:**

- o anytime during use
- o without warning symptoms
- o that may cause death

The risk of getting an ulcer or bleeding increases with:

- o past history of stomach ulcers or stomach or intestinal bleeding with the use of NSAIDs
- o taking medicines called “corticosteroids”, “anticoagulants”, “SSRIs”, or “SNRIs”
- o increasing doses of NSAIDs
- o longer use of NSAIDs
- o smoking
- o drinking alcohol
- o older age
- o poor health
- o advanced liver disease
- o bleeding problems

You should take Ibuprofen and famotidine tablets exactly as prescribed, at the lowest dose possible and for the shortest time needed.

Ibuprofen and famotidine tablets contain a non-steroidal anti-inflammatory drug NSAID (ibuprofen). Do not use ibuprofen and famotidine tablets with other medicines to lessen pain or fever or with other medicines for colds or sleeping problems without talking to your healthcare provider first, because they may contain an NSAID also.

Ibuprofen and famotidine tablets may help your acid-related symptoms, but you could still have serious stomach problems. Talk with your healthcare provider.

Ibuprofen and famotidine tablets contain ibuprofen, an NSAID and famotidine, a histamine H₂-receptor blocker medicine.

What are ibuprofen and famotidine tablets?

Ibuprofen and famotidine tablets are a prescription medicine used to:

- relieve the signs and symptoms of rheumatoid arthritis and osteoarthritis.
- decrease the risk of developing ulcers of the stomach and upper intestines (upper gastrointestinal ulcers) in people taking ibuprofen for rheumatoid arthritis and osteoarthritis.

It is not known if ibuprofen and famotidine tablets are safe and effective in children.

Do not take ibuprofen and famotidine tablets:

- if you are allergic to ibuprofen, famotidine, any other histamine H₂-receptor blocker or any of the ingredients in ibuprofen and famotidine tablets. See the end of this Medication Guide for a complete list of ingredients.
- if you have had an asthma attack, hives or other allergic reaction with aspirin or any other NSAIDs.
- right before or after heart bypass surgery.

Before taking ibuprofen and famotidine tablets, tell your healthcare provider about all of your medical conditions, including if you:

- have liver or kidney problems.
- have high blood pressure.
- have heart problems.
- have asthma.
- have bleeding problems.
- are pregnant or plan to become pregnant. Taking ibuprofen and famotidine tablets at about 20 weeks of pregnancy or later may harm your unborn baby. If you need to take ibuprofen and famotidine tablets when you are between 20 weeks and 30 weeks of pregnancy, your healthcare provider may need to monitor the amount of fluid in your womb around your baby. **You should not take ibuprofen and famotidine tablets after about 30 weeks of pregnancy.**
- are breastfeeding or plan to breast feed. Ibuprofen and famotidine can pass into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you take ibuprofen and famotidine tablets.

Tell your healthcare provider about all of the medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements. Ibuprofen and famotidine tablets and some other medicines can interact with each other and cause serious side effects. **Do not start taking any new medicine without talking to your healthcare provider first.**

How should I take ibuprofen and famotidine tablets?

- Take ibuprofen and famotidine tablets exactly as your healthcare provider tells you to take it.
- Your healthcare provider will tell you how many ibuprofen and famotidine tablets to take and when to take it.
- Do not change your dose or stop ibuprofen and famotidine tablets without first talking to your healthcare provider.
- Swallow ibuprofen and famotidine tablets whole with liquid. Do not split, chew, crush or dissolve the ibuprofen and famotidine tablet. Tell your healthcare provider if you cannot swallow the tablet whole. You may need a different medicine.
- If you forget to take your dose of ibuprofen and famotidine tablets, take it as soon as you remember. If it is almost time for your next dose, do not take the missed dose. Take the next dose on time. Do not take 2 doses at one time to make up for a missed dose.
- You should not take an ibuprofen tablet and famotidine tablet together instead of taking ibuprofen and famotidine tablets, because they will not work in the same way.

What are the possible side effects of ibuprofen and famotidine tablets?

Ibuprofen and famotidine tablets can cause serious side effects, including:

See “What is the most important information I should know about ibuprofen and famotidine tablets?”

- heart attack
- stroke
- liver problems including liver failure
- new or worse high blood pressure
- heart failure
- kidney problems including kidney failure
- life-threatening allergic reactions
- asthma attacks in people who have asthma
- life-threatening skin reactions
- low red blood cells (anemia)

Other side effects of ibuprofen and famotidine tablets include: stomach pain, constipation, diarrhea, gas, heartburn, nausea, vomiting and dizziness.

Get emergency help right away if you get any of the following symptoms:

- shortness of breath
- chest pain
- weakness in one part or side of your body
- slurred speech
- swelling of the face or throat

Stop taking ibuprofen and famotidine tablets and call your healthcare provider right away if you get any of the following symptoms:

- nausea
- more tired or weaker than usual
- diarrhea
- itching
- your skin or eyes look yellow
- indigestion or stomach pain
- flu-like symptoms
- vomit blood
- there is blood in your bowel movement or it is black and sticky like tar
- unusual weight gain
- skin rash or blisters with fever
- swelling of the arms, legs, hands and feet

If you take too much ibuprofen and famotidine tablets, call your poison control center at 1-800-222-1222.

These are not all the possible side effects of ibuprofen and famotidine tablets. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Other information about NSAIDs

- Aspirin is an NSAID but it does not increase the chance of a heart attack. Aspirin can cause bleeding in the brain, stomach and intestines. Aspirin can also cause ulcers in the stomach and intestines.
- Some NSAIDs are sold in lower doses without a prescription (over-the-counter). Talk to your healthcare provider before using over-the-counter NSAIDs for more than 10 days.

General information about the safe and effective use of ibuprofen and famotidine tablets

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use ibuprofen and famotidine tablets for a condition for which it was not prescribed. Do not give ibuprofen and famotidine tablets to other people, even if they have the same symptoms that you have. It may harm them.

You can ask your pharmacist or healthcare provider for information about NSAIDs that is written for health professionals.

What are the ingredients in ibuprofen and famotidine tablets?

Active ingredients: Ibuprofen, USP and famotidine, USP

Inactive ingredients: Colloidal silicon dioxide, croscarmellose sodium, glyceryl monocaprylocaprate type 1, hypromellose, magnesium stearate, microcrystalline cellulose, polyvinyl alcohol-partially hydrolyzed, sodium lauryl sulfate, talc and titanium dioxide.

The tablet is imprinted with black ink and contains the following inactive ingredients: black iron oxide, propylene glycol and shellac.

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