

Consumer Medicine Information

FAMOX

Famotidine

20mg & 40mg Tablets

What is in this leaflet

This leaflet answers some common questions about FAMOX. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking FAMOX against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What FAMOX is used for

FAMOX contains the active ingredient famotidine and is used to treat:

- **Peptic ulcers:**

FAMOX is used to heal peptic ulcers. Depending on the position of the ulcer it is called a gastric or duodenal ulcer. A gastric ulcer occurs in the stomach. A duodenal ulcer occurs in the duodenum, which is the tube leading out of the stomach. These ulcers usually cause pain and discomfort (indigestion), which is felt between the navel and the breastbone. The pain may occur before or after meals, or in the middle of the night.

- **Reflux disease:**

FAMOX is used to treat reflux oesophagitis, also called reflux disease. This condition is caused by the washing back, or reflux, of food and acid from the stomach into the food pipe, also called the oesophagus. This causes a painful burning sensation in the chest rising up to the throat (heartburn), and usually occurs after eating or at night.

- **Zollinger-Ellison syndrome:**

FAMOX is also used to treat Zollinger-Ellison syndrome. This is a rare condition where the stomach produces very large amounts of acid, much more than in ulcers and reflux disease, which often causes pain and discomfort.

FAMOX is also used to help stop duodenal ulcers and reflux disease from coming back.

FAMOX belongs to a group of medicines called H₂ antagonists or H₂ blockers. FAMOX works by reducing the amount of acid made by the stomach thereby reducing the pain and allowing the ulcer and/or reflux disease to heal in most people.

This medicine is only available with a doctor's prescription.

Your doctor may have prescribed FAMOX for another reason. Ask your doctor if you have any questions about why FAMOX has been prescribed for you.

FAMOX is generally not recommended for use in children, as the safety and effectiveness have not been established.

There is no evidence that FAMOX is addictive.

Before you take FAMOX

When you must not take it

Do not take FAMOX if:

- **You have an allergy to Famotidine, or any of the other ingredients listed at the end of this leaflet.**
Symptoms of an allergic reaction may include skin rash, itchiness, shortness of breath or swelling of the tongue or face.
- **You have an allergy to any other 'H2-antagonist or H2-blocker' medicines.**
If you have had an allergic reaction to any of these before, you may be allergic to FAMOX.
- **You are breast-feeding**
FAMOX passes into breast milk and therefore there is a possibility that the breast-fed baby may be affected.
- **The packaging is torn or shows signs of tampering or the tablets do not look quite right.**
- **The expiry date (Exp.) printed on the pack has passed.**
If you take this medicine after the expiry date has passed, it may not work as well.

If you are not sure whether you should start taking FAMOX, talk to your doctor.

Before you start to take it

Tell your doctor if:

- **You are pregnant, intend to become pregnant or plan to breast-feed**
Like many medicines, FAMOX is not recommended for use during pregnancy. If there is a need to consider FAMOX during your pregnancy, your doctor will discuss with you the benefits and risks of using it. FAMOX passes into breast milk.
- **You have kidney disease.**
- **You have or have ever had any other medical conditions or health problems.**
- **You have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes.**

If you have not told your doctor about any of the above, tell them before you take FAMOX.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may affect the way other medicines work.

FAMOX has not been shown to interfere with other medicines.

How to take FAMOX

How much to take

Take FAMOX only when prescribed by your doctor. Your doctor will tell you how many tablets you need to take each day. This depends on your condition.

Usually the doses are as follows:

Duodenal ulcers:

Initially: one 40mg tablet taken at night.

Maintenance (to stop ulcers from coming back): one 20mg tablet taken at night

Gastric (stomach) ulcers:

Initially: one 40mg tablet taken at night.

Maintenance (to stop ulcers from coming back): one 20mg tablet taken at night

Zollinger-Ellison syndrome:

The dose will depend on your condition and how much acid your stomach makes. Your doctor will decide the dose that is best for you.

Reflux disease:

The usual dose is one 20mg tablet taken twice a day.

It is important to carefully follow all directions given to you by your doctor or pharmacist.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

When to take it

If you are taking one dose a day, take the tablet at night. If you are taking two doses a day, take one tablet in the morning and one at night. FAMOX can be taken with or without food.

Swallow your FAMOX tablets whole with a glass of water.

Take your FAMOX at about the same time each day. This will help you remember when to take your tablets.

How long to take it

Your doctor will advise you how long to take your tablets. It is important you follow their directions carefully.

Peptic ulcers:

Usually for peptic ulcers (ulcers in the stomach or duodenum), you will need to take FAMOX for 4 to 8 weeks. However; your doctor will tell you for how long you should continue to take the tablets.

Sometimes you need more than 8 weeks treatment with FAMOX to stop the ulcer from coming back. Your doctor will decide if you need more treatment.

Reflux disease and Zollinger-Ellison syndrome:

For the treatment of reflux disease and Zollinger-Ellison syndrome, you usually need to take FAMOX for a longer period of time. Your doctor will let you know how long you need to take the tablets.

Do not stop taking FAMOX just because you feel better.

Stopping your tablets too early may let the ulcer come back.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember, and then go back to taking your tablet(s) as you would normally.

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

Do not take a double dose to make up for the dose that you missed.

If you have trouble remembering to take your tablets, ask your pharmacist for some hints.

While you are taking FAMOX

Things you must do

If you become pregnant while taking FAMOX, tell your doctor.

If you are about to start taking a new medicine tell your doctor and pharmacist that you are taking FAMOX.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking FAMOX.

If you do not notice any improvement in your condition or the symptoms get worse, tell your doctor or pharmacist.

Things you must not do

Do not stop taking your tablets if you are feeling better, unless advised to do so by your doctor.

If you do not complete the full course prescribed by your doctor your symptoms may return.

Do not give FAMOX to anyone else, even if they have the same condition as you.

Do not use FAMOX to treat any other complaints you may have unless your doctor tells you to.

Things to be careful of

Be careful driving or operating machinery until you know how FAMOX affects you.

FAMOX generally does not cause any problems with your ability to drive a car or operate machinery. However, as with many other medicines, FAMOX may cause dizziness in **some** people. Make sure you know how you react to FAMOX before you drive a car or operate machinery.

Things that may help your condition

Some self help measures suggested below may help your condition. Talk to your doctor or pharmacist about these measures and for more information.

- **Alcohol**
Your doctor may advise you to limit your alcohol intake.
- **Aspirin and many other medicines used to treat arthritis/period pain/headache**
These medicines may irritate the stomach and may make your condition worse. Your doctor or pharmacist may suggest other medicines you can take.

- **Caffeine**
Your doctor may advise you to limit the number of drinks that contain caffeine, such as coffee, tea, cocoa and cola drinks, because these contain ingredients that may irritate your stomach.
- **Eating habits**
Eat smaller, more frequent meals. Eat slowly and chew your food carefully. Try not to rush at meal times.
- **Food**
Avoid foods that cause you pain or discomfort.
- **Smoking**
Your doctor may advise you to stop smoking or at least cut down.
- **Weight**
Your doctor may suggest losing some weight to help your condition.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking FAMOX.

FAMOX helps most people with ulcers or reflux disease, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- Headache
- Dizziness
- Constipation, diarrhoea, abdominal discomfort
- Nausea and/or vomiting
- Fatigue
- Muscle aches or pain
- Changes in mood, depression, confusion and hallucinations
- Dry mouth, taste disorder
- Unusual hair loss or thinning
- Bleeding or bruising more easily than normal
- Frequent infections such as fever, severe chills, sore throat or mouth ulcers
- Loss of appetite.

These are generally mild side effects and may occur in a very small number of people.

Rarely, more serious side effects may occur. If any of the following happen, stop taking FAMOX and tell your doctor immediately or go to accident and emergency at your nearest hospital:

- Swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing
- Swelling of the hands, feet, or ankles
- Any severe skin reaction, particularly blisters and bleeding in the lips, eyes, nose, mouth and genitals
- Hives or nettlerash (pinkish, itchy swellings on the skin)
- Yellowing of the skin and/or eyes, also called jaundice

- Convulsions
- Shortness of breath.

These may be some of the serious side effects. If you have them, you may have an allergic reaction to FAMOX. You may need urgent medical attention or hospitalisation. These side effects are rare.

Other side effects not listed above may also occur in some patients. Tell your pharmacist or doctor if you notice any other effects.

Do not be alarmed by this list of possible side effects. They do not occur often and you are unlikely to experience any of them.

In case of overdose

You should only take the number of tablets that you have been told.

Immediately contact your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) or go to the Emergency department at your nearest hospital, if you think that you may have taken too much, or if anyone else has taken any FAMOX by mistake. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Take the container of FAMOX with you if you can.

Keep telephone numbers for these places handy.

After using FAMOX

Storage

Keep your tablets in the bottle or pack until it is time to take them.

If you take the tablets out of the blister pack or bottle they may not keep well.

Keep FAMOX in a cool dry place where the temperature stays below 25°C.

Do not store it or any other medicines in the bathroom or near a sink.

Do not leave it in the car or on windowsills.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking FAMOX or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

FAMOX tablets comes in two strengths:

- FAMOX 20 - beige coloured, rounded square-shaped tablet with FM20 marked on one side and G on the other side
- FAMOX 40 - caramel coloured, rounded square-shaped tablet with FM40 marked on one side and G on the other side

Ingredients

Active ingredient:

Each FAMOX 20 tablet contains 20 mg famotidine

Each FAMOX 40 tablet contains 40 mg famotidine

Inactive ingredients:

- Pregelatinised maize starch
- Magnesium stearate
- Purified talc
- Microcrystalline cellulose
- Hypromellose
- Titanium dioxide
- Macrogol 400
- Red iron oxide (E172)
- Yellow iron oxide (E172)

The 40 mg tablet also contains black iron oxide (E172)

The tablets are polished with carnauba wax.

FAMOX does not contain gluten, lactose or sugar.

If you want to know more

Should you have any questions regarding this product, please contact your doctor or pharmacist.

Who supplies this medicine

Distributed in New Zealand by:

Mylan New Zealand Ltd,
P O Box 11183,
Ellerslie,
Auckland.

Telephone (09) 579 2792

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10 March 2010

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