

GenRx Famotidine

Contains the active ingredient famotidine

Consumer Medicine Information

For a copy of a large print leaflet,
Ph: 1800 195 055

What is in this leaflet

Read this leaflet carefully before taking your medicine.

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

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up to date leaflet from www.apotex.com.au.

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

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

What this medicine is used for

The name of your medicine is GenRx Famotidine Tablets. It contains the active ingredient famotidine.

Famotidine belongs to a group of medicines called H2-antagonists. It is used to:

It is used to:

- Treat peptic ulcers.
Depending on the position of the ulcer it is called a gastric or duodenal ulcer. A gastric ulcer occurs in the stomach and a duodenal ulcer occurs in the duodenum, which is the tube leading from the stomach. These ulcers usually cause pain and indigestion which is felt between the navel and the breast bone. The pain may occur before or after meals, or in the middle of the night. Famotidine also helps to stop duodenal ulcers coming back.
- Treat Zollinger Ellison Syndrome, a rare condition caused by too much acid production in the stomach.
- Treat and relieve symptoms of Gastro-Oesophageal Reflux Disease.
This is caused by the reflux, or washing back, of food and acid from the stomach, into the oesophagus (food pipe). It causes a painful burning feeling in the chest which rises to the throat (heartburn), and usually occurs after eating or at night. It also helps to stop these symptoms from coming back.

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

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

How it works

Famotidine belongs to a group of medicines called H2-antagonists or H2-blockers. It works by reducing the amount of acid in the stomach thereby reducing the pain and allowing the ulcer to heal.

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

There is no evidence that this medicine is addictive.

Use in children

This medicine should not be used in children.

Before you take this medicine

When you must not take it

Do not take this medicine if:

- **You have or have had any of the following:**
- **You are pregnant.**
Famotidine may affect your developing baby if you take it during pregnancy.
- **You are breastfeeding.**
Famotidine may pass into human breast milk.

- You are hypersensitive to, or have had an allergic reaction to, famotidine, any other type of H2- antagonist/blocker medicines or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include: cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin; fainting; or hay fever-like symptoms.

If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

- The expiry date (EXP) printed on the pack has passed.
- The packaging is torn, shows signs of tampering or it does not look quite right.

Before you start to take it

Before you start taking this medicine, tell your doctor if:

1. You have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:
 - kidney disease
 - cancer of the stomach
 - chronic lung disease
 - diabetes
 - you are immunocompromised.
3. You are currently pregnant or you plan to become pregnant. Do not take this medicine whilst pregnant until you and your doctor have discussed the risks and benefits involved.

4. You are currently breastfeeding or you plan to breast-feed. Do not take this medicine whilst breastfeeding until you and your doctor have discussed the risks and benefits involved.
6. You are planning to have surgery or an anaesthetic.
7. You are currently receiving or are planning to receive dental treatment.
8. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Some medicines may affect the way other medicines work.

How to take this medicine

Follow carefully all directions given to you by your doctor. Their instructions may be different to the information in this leaflet.

How much to take

Your doctor will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

- **Duodenal Ulcers:**
To heal duodenal ulcers the usual adult dose is one 40mg tablet taken at night. To help stop these ulcers coming back the usual dose is one 20mg tablet taken at night.
- **Gastric (Stomach) Ulcers:**
To heal gastric ulcers the usual dose is one 40mg tablet daily, taken at night.
- **Zollinger-Ellison Syndrome:**
Your doctor will determine the dose, depending on how much acid your stomach produces.

- **Gastro-Oesophageal Reflux Disease:**

To treat this, or to help stop it coming back, the usual dose is one 20 mg tablet taken twice daily.

People with kidney problems may need lower doses.

Do not stop taking your medicine or change your dosage without first checking with your doctor or pharmacist.

How to take it

Swallow your tablets whole with a glass of water.

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.

Take it at about the same time each day.

Taking your medicine at the same time each day will have the best effect. It will also help you remember when to take it.

It does not matter if you take it before, with or after food.

How long to take it for

Continue taking your medicine for as long as your doctor tells you.

Make sure you have enough to last over weekends and holidays.

For peptic ulcers (ulcers in the stomach or duodenum), you will need to take famotidine tablets for 4 to 8 weeks. Do not stop taking the tablets too early unless your doctor tells you to, as your ulcer may reoccur. To stop duodenal ulcers coming back, you may need more than 8 weeks of treatment.

For the treatment of reflux disease and Zollinger-Ellison Syndrome, you may need to take famotidine tablets for a longer period.

Your doctor will advise you how long to take your tablets for.

If you forget to take it

If it is almost time to take your next dose, skip the missed dose and take your next dose at the usual time. Otherwise, take it as soon as you remember and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for missed doses.

This may increase the chance of you experiencing side effects.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints to help you remember.

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively, go to the Accident and Emergency department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are taking this medicine

Things you must do

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you are pregnant or are planning to become pregnant
- you are breastfeeding or are planning to breast-feed
- you are about to have any blood tests
- you are going to have surgery or an anaesthetic or are going into hospital

Go to your doctor regularly for a check-up.

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

Things you must not do

Do not:

- Give this medicine to anyone else, even if their symptoms seem similar to yours.
- Take your medicine to treat any other condition unless your doctor or pharmacist tells you to.
- Stop taking your medicine, or change the dosage, without first checking with your doctor.

Things to be careful of

Be careful when driving or operating machinery until you know how this medicine affects you.

Famotidine tablets do not normally cause any problems with your ability to drive a car or operate machinery. However, as with many other medicines, famotidine may cause dizziness in some people. Make sure you know how you react to famotidine 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 pharmacist or doctor may advise you to limit your alcohol intake.
- Aspirin and many other medicines used to treat arthritis/period pain/headaches - these medicines may irritate the stomach and may make your condition worse. Your pharmacist or doctor may suggest other medicines you can take.

- Caffeine - your pharmacist or doctor may advise you to limit the number of drinks which 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 pharmacist or doctor may advise you to stop smoking or at least cut down on smoking.
- Weight - your pharmacist or doctor may suggest losing some weight to help your condition.

Possible side effects

Tell your doctor as soon as possible if you do not feel well while you are taking famotidine or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

Tell your doctor if you notice any of the following:

- headache
- dizziness
- diarrhoea, constipation.

Tell your doctor as soon as possible if you notice any of the following.

These may be serious side effects and you may need medical attention:

- nausea, vomiting, abdominal discomfort or swelling, anorexia, dry mouth
- fever, fatigue
- abnormal test results for blood cell levels
- irregular or rapid heart beat, palpitations

- muscle pain, cramps, painful joints
- hallucinations, confusion, agitation, depression, anxiety, inability to sleep, sleepiness, tingling in the fingers or toes, decreased sexual drive, fits
- breathing difficulties caused by narrowing of the airways, or pneumonia (infection of the lungs)
- ringing in the ears, taste disorders
- acne, dry skin, flushing, loss of hair.

If you experience any of the following, stop taking your medicine and contact your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

These are very serious side effects and you may need urgent medical attention or hospitalisation:

- swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing
- fluid-filled blisters on the skin or on the lips or genitals or in the eyes, nose or mouth
- swelling of the hands, feet or ankles
- any severe skin reaction (skin rash, itchiness, redness, skin ulcers, a scalded appearance)
- hives or nettle rash (pinkish, itchy swellings on the skin)
- yellowing of the skin and/or eyes, also called jaundice
- fits (convulsions), especially in people with kidney problems.

Other side effects not listed above may occur in some patients.

Allergic reactions

If you think you are having an allergic reaction to famotidine, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- cough, shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue, throat or other parts of the body
- rash, itching or hives on the skin
- fainting
- hay fever-like symptoms.

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 30°C.

Do not store your medicine, or any other medicine, in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep this medicine 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 this medicine or it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What GenRx Famotidine Tablets looks like

- **GenRx Famotidine 20 mg tablets:**

A beige, round, biconvex tablet embossed with 20 on one face and plain on the other.
Packs of 60 tablets.

- **GenRx Famotidine 40 mg tablets:**

A brown, round, biconvex tablet embossed with 40 on one face and plain on the other.
Packs of 30 tablets.

* Not all strengths, pack types and/or pack sizes may be available.

Ingredients

Each tablet contains 20 mg or 40 mg of famotidine as the active ingredient.

It also contains the following inactive ingredients:

- pregelatinised maize starch
- microcrystalline cellulose
- magnesium stearate
- purified talc
- Opadry™ Buff OY-3690 (20 mg only)
- Opadry™ Buff OY-3682 (40 mg only).

This medicine is gluten-free, lactose-free, sucrose-free, tartrazine-free and free of other azo dyes.

Australian Registration Numbers

- GenRx Famotidine 20mg tablets (blister pack):
AUST R 91513.
- GenRx Famotidine 40mg tablets (blister pack):
AUST R 91514.

Sponsor

Apotex Pty Ltd
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