

Famotidine AN tablets

Famotidine

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Famotidine AN.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

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

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

Keep this leaflet with your medicine.

You may need to read it again.

What Famotidine AN is used for

Famotidine AN tablets belong to a group of medicines called H₂-antagonists. They are used for:

- Treat stomach and duodenal ulcer disease (also known as peptic ulcer) and stop ulcers coming back.
- Treat Zollinger-Ellison Syndrome (rare condition caused by too much acid production in the stomach).

Famotidine AN works by reducing the amount of acid in the stomach thereby reducing the pain and allowing the ulcer to heal.

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

prescribed for you.

Do not take Famotidine AN to treat any other complaints unless your doctor has instructed you to do so.

Famotidine AN is only available with a doctor's prescription.

Famotidine AN should not be given to children under 18 years of age as there is limited experience with the use of famotidine in children.

There is no evidence that Famotidine AN tablets are addictive.

Before You Take Famotidine AN

Do not take Famotidine AN if:

- You have an allergy to famotidine or to any of the ingredients listed at the end of this leaflet. Symptoms of an allergic reaction may include, shortness of breath, swelling of the tongue or face, skin rash and itchiness.
- You are breast-feeding or plan to breast-feed. Famotidine AN passes into breast milk. There is a possibility that this may affect your breast-fed baby.
- The expiry date (EXP) on the pack has passed. If you take this medicine after the date has passed it may have no effect at all, or worse, an entirely unexpected effect.
- The packaging is torn or shows signs of tampering.

If you are not sure whether you should take Famotidine AN, talk to your doctor or pharmacist

Tell your doctor if:

- You are pregnant, plan to become pregnant or to breastfeed. Like most medicines, Famotidine AN is not recommended for use during pregnancy.
- You have kidney disease
- You are allergic to any medicine
- You are allergic to any other substances such as foods, dyes or preservatives.
- You have or have ever had any other health problems.

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking Famotidine AN.

Taking other medicines

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

Some medicines may affect the way other medicines work. Famotidine AN has not been shown to interfere with other medicines.

How to take Famotidine AN

Carefully follow all directions given to you by your doctor and 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.

How much to take

The dosage depends on the disease that you are suffering from. Your doctor or pharmacist will tell you how many Famotidine AN tablets to take and how often to take them.

When to take it

It is preferable for you to take the tablets at the same time each day. It will help you to remember when to take your tablets.

Famotidine AN tablets should be swallowed whole with a glass of water and may be taken before or after food.

How long to take it

For peptic ulcers (ulcers in the stomach or duodenum), you will need to take Famotidine AN tablets for 4 to 8 weeks. Do not stop taking the tablets too early as your ulcer may reoccur. In some cases, you may need more than 8 weeks treatment.

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

Your doctor will advise you how long to take your tablets

If you forget to take it

If it is almost time to take your next dose, skip the dose that you missed and take your next dose when you are meant to. Otherwise take it as soon as you remember, then go back to taking your tablets as usual.

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

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

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

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much Famotidine AN. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Keep telephone numbers of these places/services handy.

While you are taking Famotidine AN

Things you must do

If you are pregnant or likely to become pregnant while you are taking Famotidine AN tablets, tell your doctor.

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

If your stomach discomfort continues, tell your doctor. If your symptoms continue for more than 5 days, or your symptoms come back within two weeks of completing a course of Famotidine AN, tell your doctor or pharmacist

Things you must not do

Do not stop taking your tablets because 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 Famotidine AN to anyone else even if they have the same condition as you.

Do not use Famotidine AN to

treat any other complaints unless your doctor tells you to.

Things to be careful of

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

Famotidine AN tablets do not normally cause any problems with your ability to drive a car or operate machinery. However, as with many other medicines, Famotidine AN may cause dizziness in some people.

Make sure you know how you react to Famotidine AN 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 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.

Side Effects

Check with your doctor or pharmacist as soon as possible if you have any problems while you are taking Famotidine AN, even if you do not think that the problems are connected with the medicine or are not listed in this leaflet.

Like all medicines, Famotidine AN can cause side effects. If they occur, most are likely to be minor and temporary. However, some may be serious and need medical attention.

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
- Diarrhoea, constipation, nausea, vomiting, abdominal discomfort, anorexia, dry mouth
- Fever, fatigue
- Irregular or rapid heart beat, palpitations
- Muscle pain, cramps, painful joints
- Hallucinations, confusion, agitation, depression, anxiety, inability to sleep, sleeplessness, tingling in the fingers or toes, decreased sex drive, fits
- Breathing difficulties caused by narrowing of the airways
- Ringing in the ears
- Taste disorders
- Acne, dry skin, flushing, loss of hair

These are generally mild side effects.

Rarely, more serious side

effects may occur. If you experience any of the following, stop taking Famotidine AN, tell your doctor immediately or go to casualty 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 (skin rash, itchiness)
- Hives or nettle rash (pinkish, itchy swellings on the skin)
- Yellowing of the skin and/or eyes, also called jaundice

These may be some of the serious side effects. If you have them, you may have an allergic reaction to Famotidine AN. 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 doctor or pharmacist if you notice any of these effects.

Do not be alarmed by this list of possible side effects you may not experience any of them.

After taking Famotidine AN

Storage

Keep your tablets in the blister pack until it is time to take them. If you take the tablets out of the blisters they may not keep as well.

Keep Famotidine AN in a cool dry place away from direct sunlight where the temperature stays below 30°C.

Do not store Famotidine AN or any other medicine in the bathroom or near a sink.

Do not leave Famotidine AN in the car or on windowsills.

Heat and dampness can destroy some medicines.

Keep Famotidine AN 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 Famotidine AN, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

Famotidine AN 20 mg & 40 mg tablets are presented in pack sizes of 30 & 100 tablets in a PVC/PVDC/Al blister.

Famotidine AN 20 mg (AUST R 186280)

Beige, round, biconvex tablets with '20' on one face and plain on the other side.

Famotidine AN 40 mg (AUST R 186281)

Brown, round, biconvex tablets with '40' on one face and plain on the other side.

Ingredients

Active Ingredient:

Famotidine

Each tablet may contain either 10mg or 20 mg of Famotidine

Other Ingredients:

- Pregelatinised maize starch
- Microcrystalline cellulose
- Magnesium stearate
- Purified talc
- Opadry Buff OY-3690 (20 mg)
- Opadry Buff OY-3682 (40 mg)

Please read this leaflet carefully before you start taking Famotidine AN. You may wish to keep it to read again.

Name and Address of the Sponsor

Amneal Pharma Australia Pty
Ltd
12 River St
South Yarra
Vic - 3141
Australia

Date of Preparation

September 2014