

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about AUSFAM.

It does not contain all 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 AUSFAM 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 AUSFAM is used for

AUSFAM is used to:

- treat peptic ulcers (gastric and duodenal ulcers)
- treat reflux oesophagitis (reflux disease)
- treat a rare condition called Zollinger-Ellison syndrome
- prevent duodenal ulcers and reflux disease from coming back.

Peptic ulcers:

AUSFAM 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 breast bone. The pain may occur before or after meals, or in the middle of the night.

AUSFAM is also used to help stop duodenal ulcers from coming back.

Reflux disease:

AUSFAM is used to treat reflux oesophagitis, also called reflux disease, and stop it from coming back. 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:

AUSFAM is used to treat a rare condition called Zollinger-Ellison syndrome, where the stomach produces very large amounts of acid, much more than in ulcers and reflux disease.

AUSFAM belongs to a group of medicines called histamine H2-antagonists. These medicines work by reducing the amount of acid made by the stomach. This helps reduce the pain and also allows the ulcer and/or reflux disease to heal in most people.

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

AUSFAM is not recommended for use in children, as the safety and effectiveness of this drug have not been established in children.

AUSFAM is available only with a doctor's prescription.

There is no evidence that AUSFAM is addictive.

Before you take AUSFAM

When you must not take it

Do not take AUSFAM if you are allergic to:

- medicines containing famotidine
- any other histamine H2-antagonist medicine
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include skin rash, itchiness or hives, swelling of the face, lips or tongue (which may cause difficulty in swallowing), shortness of breath, wheezing or difficulty breathing.

Do not take AUSFAM if you are breastfeeding.

AUSFAM passes into breast milk and may affect your baby.

Do not take AUSFAM if 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.

Do not take AUSFAM if the packaging shows signs of tampering or the tablets do not look quite right.

Before you start to take it

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

Tell your doctor if you are pregnant or plan to become pregnant.

Your doctor will discuss the risks and benefits of taking AUSFAM during pregnancy.

Tell your doctor if you have kidney problems or any other medical conditions.

If you have not told your doctor about any of the above, tell them before you start taking AUSFAM.

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. However, AUSFAM has not been shown to interfere with other medicines.

How to take AUSFAM

How much to take

Your doctor will tell you how many tablets you need to take each day and when to take them. This depends on your condition.

To heal peptic ulcers, the usual dose is one 40 mg tablet taken at night.

To help stop duodenal ulcers from coming back, the usual dose is one 20 mg tablet taken at night.

For Zollinger-Ellison syndrome the dose depends on how much acid your stomach is producing. Your doctor will decide how much you need to take.

The usual dose for the treatment and maintenance of reflux disease is one 20 mg tablet taken twice a day.

If you have kidney disease, the doctor may prescribe a lower dose.

Follow all directions given to you by your doctor and pharmacist carefully.

If you forget to take AUSFAM

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 the missed dose as soon as you remember, and then go back to taking your tablets as you would normally.

Do not take two doses at a time to make up for the dose you missed.

If you are not sure what to do, ask your doctor or pharmacist.

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 dose in the morning and one at night.

AUSFAM can be taken with or without food.

Swallow AUSFAM with a glass of water.

How long to take AUSFAM

For peptic ulcers, AUSFAM needs to be taken for 4 to 8 weeks.

Do not stop taking AUSFAM, even if you feel better unless advised by your doctor.

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

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

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

Keep taking AUSFAM for as long as your doctor recommends.

If you take too much AUSFAM (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much AUSFAM. Do this even

if there are no signs of discomfort or poisoning.

While you are taking AUSFAM

Things you must do

Before starting any new medicine, tell your doctor or pharmacist that you are taking AUSFAM.

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

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

If you develop sudden onset of fever, rigors and shortness of breath, and/or a dry cough that becomes productive with 'rusty' and green sputum, tell your doctor immediately.

Visit your doctor regularly so they can check on your progress.

Things you must not do

Do not use AUSFAM to treat any other conditions unless your doctor tells you to. Do not give AUSFAM to anyone else, even if they have the same condition as you.

Things to be careful of

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

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

Suggestions that may help your condition

Some self help measures suggested below may help your condition. Talk to your doctor or pharmacist about these measures or 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 or headache – these medicines may irritate the stomach and 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 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 doctor or pharmacist may advise you to stop smoking or at least cut down.

Side effects

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

Like all other medicines, AUSFAM may have unwanted side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

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

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.

These are generally mild side effects.

If any of the following happen, stop taking AUSFAM and tell your doctor immediately, or go to Accident and Emergency at the 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
- hives or nettle rash (pinkish, itchy swellings on the skin)
- yellowing of the skin and/or eyes (jaundice).

These are serious but rare side effects.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything that is making you feel unwell.

After using AUSFAM

Storage

Keep AUSFAM 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.

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

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

Keep your tablets in a cool dry place where the temperature stays below 30°C.

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

Do not leave AUSFAM in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking AUSFAM, 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

AUSFAM comes in 2 strengths of tablets:

- AUSFAM 20 – square, tan tablet marked “FO over 20” and “>” on the reverse. Each blister pack contains 60 tablets.
- AUSFAM 40 – square, brown tablet marked “FO over 40” and “>” on the reverse. Each blister pack contains 30 tablets.

Ingredients

The active ingredient in AUSFAM is famotidine.

- each AUSFAM 20 tablet contains 20 mg of famotidine
- each AUSFAM 40 tablet contains 40 mg of famotidine.

The tablets also contain:

- microcrystalline cellulose
- pregelatinised maize starch
- purified talc
- magnesium stearate
- Opadry Brown 03B56615 (20 mg tablets)
- Opadry Brown 03B56611 (40 mg tablets).

The tablets are gluten free.

Manufacturer

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Australian registration numbers:
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