

AUSFAM

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using AUSFAM?

Ausfam contains the active ingredient famotidine. 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

For more information, see Section [1. Why am I using AUSFAM?](#) in the full CMI.

2. What should I know before I use AUSFAM?

Do not use if you have ever had an allergic reaction to famotidine or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use AUSFAM?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with AUSFAM and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use AUSFAM?

- Your doctor will tell you how many tablets you need to take each day. This depends on your condition.
- Please follow your doctor's instructions about how and when to take AUSFAM

More instructions can be found in Section [4. How do I use AUSFAM?](#) in the full CMI.

5. What should I know while using AUSFAM?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using AUSFAM.• Before starting any new medicine, tell your doctor or pharmacist that you are taking AUSFAM.
Things you should not do	<ul style="list-style-type: none">• Do not use this medicine to treat any other conditions unless your doctor tells you to.• Do not give it to anyone else, even if they have the same condition as you.• Do not stop using this medicine even if you feel better unless advised by your doctor. Stopping your tablets too early may let the ulcer come back.
Driving or using machines	<ul style="list-style-type: none">• Be careful driving or operating machinery until you know how AUSFAM affects you. It may cause dizziness, headache, confusion or hallucination in some people. Patients should be informed that they should avoid driving vehicles or operating machinery or doing activities which require prompt vigilance if they experience these symptoms.
Drinking alcohol	<ul style="list-style-type: none">• Your doctor may advise you to limit your alcohol intake.
Looking after your medicine	<ul style="list-style-type: none">• Keep your medicine where children cannot reach it.• Keep your tablets in a cool dry place where the temperature stays below 30°C.• 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.

For more information, see Section [5. What should I know while using AUSFAM?](#) in the full CMI.

6. Are there any side effects?

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.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

AUSFAM

Active ingredient: *Famotidine*

Consumer Medicine Information (CMI)

This leaflet provides important information about using AUSFAM. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using AUSFAM.**

Where to find information in this leaflet:

- [1. Why am I using AUSFAM?](#)
- [2. What should I know before I use AUSFAM?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use AUSFAM?](#)
- [5. What should I know while using AUSFAM?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using AUSFAM?

AUSFAM contains the active ingredient famotidine.

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.

AUSFAM 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. 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 ulcer 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.

Your doctor may have prescribed this medicine for another reason.

Ask your doctor if you have any questions about why it 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.

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

There is no evidence that it is addictive.

2. What should I know before I use AUSFAM?

Warnings

Do not use AUSFAM if:

- you are allergic to famotidine, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- any other histamine H2-antagonist medicine.
- The expiry date printed on the pack has passed
- The packaging is torn or shows signs of tampering or the tablets do not look quite right.

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.

Check with your doctor if you:

- are breastfeeding. This medicine passes into breast milk and may affect your baby.
- Have kidney problems or any other medical conditions.
- are allergic to any other medicines, foods, dyes or preservatives.
- have not told your doctor about any of the above, tell them before you start taking AUSFAM.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

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.

- 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 mealtimes.
- 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.

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. Your doctor will discuss the risks and benefits of taking AUSFAM during pregnancy.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

This medicine passes into breast milk and may affect your baby.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop. Some medicines may affect the way other medicines work.

Some medicines which may interfere with Ausfam and affect how it works.

- Famotidine may decrease the effect of posaconazole oral suspension (a drinkable medicine used to prevent and treat some fungal infections)
- Famotidine may decrease the effect of dasatinib, erlotinib, gefitinib, pazopanib (medicines used to treat cancer)
- Ketoconazole (should be administered 2 hours before Famotidine) or Itraconazole, used to treat fungal infections.
- Probenecid, used to treat gout
- Antacids, for indigestion (famotidine should be administered 1-2 hours before taking an antacid)
- Sucralfate, used to treat and prevent the recurrence of ulcers (sucralfate should not be administered after taking famotidine)
- Calcium carbonate, when used as a medicine for high blood phosphate levels in patients on dialysis
- Atazanavir, used for treatment of HIV infection
- 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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect AUSFAM.

4. How do I use AUSFAM?

How much to take / use

- Your doctor will tell you how many tablets you need to take each day and when to take them. This depends on your condition.
- Follow the instructions provided and use AUSFAM until your doctor tells you to stop.
- 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.

When to take / use AUSFAM

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 it 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 forget to use AUSFAM

AUSFAM should be used regularly at the same time each day. If you miss your dose at the usual time.

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 a double dose to make up for the dose you missed.

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

If you use too much AUSFAM

If you think that you have used too much AUSFAM, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to Accident and Emergency at the nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using AUSFAM?

Things you should do

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

Call your doctor straight away if you:

- If you become pregnant while taking this medicine, 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.

Remind any doctor, dentist or pharmacist you visit that you are using AUSFAM.

Things you should not do

- Do not stop using this medicine suddenly.
- Do not use this medicine to treat any other conditions unless your doctor tells you to.
- Do not give it to anyone else, even if they have the same condition as you.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how AUSFAM affects you.

It 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 headache, confusion or hallucination in some people. Patients should be informed that they should avoid driving vehicles or operating machinery or doing activities which require prompt vigilance if they experience these symptoms.

Drinking alcohol

Tell your doctor if you drink alcohol.

Your doctor may advise you to limit your alcohol intake.

Looking after your medicine

- Keep your tablets in the pack until it is time to take them.
- Keep your tablets in a cool dry place where the temperature stays below 30°C.
- Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

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

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Common: <ul style="list-style-type: none">• Headaches• Dizziness• Diarrhoea• Constipation	Speak to your doctor if you have any of these less serious side effects and they worry you.
Uncommon side effects <ul style="list-style-type: none">• Feeling and/or being sick (nausea/vomiting)• Abdominal pain• Excessive wind/feeling bloated (flatulence)• Tiredness (fatigue)• Dry mouth• Loss of appetite (anorexia)• Taste disorder• Severe itching (pruritus)• Rash• Urticaria	

Serious side effects

Serious side effects	What to do
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<ul style="list-style-type: none"> 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). 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects but rare side effects.</p>
<p>Very rare side effects:</p> <ul style="list-style-type: none"> Reversible psychic disturbances including: <ul style="list-style-type: none"> Hallucinations Disorientation Confusion Anxiety disorders Agitation Depression Disorders of sexual function Difficulty sleeping Chest tightness Abnormal heart rhythm where the heart beats too slowly (AV block) Disrupted heart rhythm/irregular heartbeat (arrhythmias) Heart rhythm condition that may causes a fast heartbeat (QT prolongation) (especially in patients with impaired renal function) 	

<p>Other ingredients (inactive ingredients)</p>	<ul style="list-style-type: none"> microcrystalline cellulose pregelatinised maize starch purified talc magnesium stearate Opadry Brown 03B56615 (20 mg tablets) Opadry Brown 03B56611 (40 mg tablets).
<p>Potential allergens</p>	<p>AUSFAM does not contain gluten, lactose or sucrose</p>

Do not take this medicine if you are allergic to any of these ingredients.

What AUSFAM looks like

AUSFAM 20 famotidine 20 mg tablet blister pack (Aust R 93788)

Square, tan tablet marked “FO over 20” on one side and plain on the other side. Each blister pack contains 60 tablets.

AUSFAM 40 famotidine 40 mg tablet blister pack (Aust R 93789)

Square, brown tablet marked “FO over 40” on one side and plain on the other side. Each blister pack contains 30 tablets.

Who distributes AUSFAM

Arrotex Pharmaceuticals Pty Ltd
15-17 Chapel St
Cremorne VIC 2121
www.arrotex.com.au

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Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What AUSFAM contains

<p>Active ingredient (main ingredient)</p>	<p>Famotidine</p>
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