

# FAMOHEXAL®

Famotidine tablets

## Consumer Medicine Information

### What is in this leaflet

This leaflet answers some common questions about Famohexal.

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 risk of you taking Famohexal against the benefits it is expected to 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 want to read it again.**

### What Famohexal is used for

The name of your medicine is Famohexal. It contains the active ingredient famotidine.

Famohexal is used to treat peptic ulcers (gastric and duodenal ulcers), reflux oesophagitis (reflux disease) or a rare condition called Zollinger-Ellison syndrome. It is also used to help stop duodenal ulcers and reflux disease from coming back.

### Peptic ulcers

Famohexal 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.

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

### Reflux disease

Famohexal is used to treat reflux oesophagitis (also called reflux disease), and to 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

Famohexal 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 Famohexal for another reason. Ask your doctor if you have any questions about why Famohexal was prescribed for you.**

### How Famohexal works

Famohexal belongs to a group of medicines called histamine H2 antagonists or histamine H2 blockers. Famohexal works 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.

There is no evidence that Famohexal is addictive.

### Before you take Famohexal

#### When you must not take Famohexal

#### Do not take Famohexal if:

- **You are allergic to famotidine or any of the inactive ingredients listed at the end of this leaflet under Product Description. Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips or tongue (which may cause difficulty in swallowing); skin rash, itching or hives.**
- **You are breastfeeding. Famohexal passes into breast milk and may affect your baby.**
- **It is past its expiry date or the packaging appears to have been tampered with.**

Famohexal is not recommended for use in children, as its safety and effectiveness have not been established in this group.

## *Before you start to take Famohexal*

### **Tell your doctor if you have allergies to:**

- Any other medicines, especially if they are in the same drug class as famotidine.
- Any other substances including foods, preservatives or dyes.

**Tell your doctor if you are pregnant or plan on becoming pregnant. Famohexal is not recommended for use during pregnancy. If there is a need to consider Famohexal during your pregnancy, your doctor will discuss with you the benefits and risks of using it.**

**Tell your doctor if you will be breastfeeding while you are using Famohexal.**

**Tell your doctor if you have kidney disease, lung disease, diabetes or any other medical conditions that may make you more susceptible to pneumonia.**

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

### *Taking other medicines*

**Tell your doctor if you are taking any other medicine, including any that you buy without a prescription from your pharmacy, supermarket or health food shop. Some medicines may be affected by Famohexal or may affect how well it works. However, Famohexal has not been shown to interfere with other medicines.**

---

## **How to take Famohexal**

---

Your doctor will tell you how many tablets you need to take each day. This depends on your condition. If you have impaired kidney function, your doctor may also lower your dose.

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

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

For the treatment of reflux disease the usual dose is one 20mg tablet taken twice a day.

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

**Carefully follow all directions given to you by your doctor. They may differ from the information contained in this leaflet.**

### *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.**

It does not matter if you take Famohexal with or without food.

**The tablets should be swallowed whole with a full glass of water.**

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

**If you need to break Famohexal, hold tablet with both hands and snap along break line.**

*[Insert graphic CODE - TB01]*

### *How long to take it*

**You will need to take Famohexal for 4 to 8 weeks to treat your peptic ulcer. Your doctor will tell you how long to take the tablets.**

**Do not stop taking Famohexal just because you feel better. Stopping your tablets too early may let the ulcer come back.**

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

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

### *If you forget to take your dose*

**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 your dose as soon as you remember, and continue to take it 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 have trouble remembering when to take your medicine, ask your pharmacist for some hints.**

### *If you take too much Famohexal (overdose)*

**Immediately telephone your doctor, or the Poisons Information Centre (telephone 131 126) or go to Accident and Emergency at your nearest hospital, if you think you or anyone else has taken too much Famohexal.**

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

---

## **While you are using Famohexal**

---

### *Things you must do*

- Always follow your doctor's instructions carefully.
- Visit your doctor regularly so they can check on your progress.
- Tell your doctor if you become pregnant while taking Famohexal.

- **If you are about to start taking a new medicine, tell your doctor and pharmacist that you are taking Famohexal.**

### *Things you must not do*

- **Do not stop taking Famohexal without your doctor's permission.**
- **Do not use Famohexal to treat any other complaint unless your doctor says so.**
- **Do not give this medication to anyone else, even if their symptoms seem similar to yours.**

### *Things to be careful of*

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

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

Suggestions that may help your condition

**Below are some self help measures that may help your condition. Talk to your doctor or pharmacist for more information.**

**Alcohol** - your doctor or pharmacist may advise you to limit your alcohol intake.

Aspirin and many other medicines used to treat arthritis, period pain, and headache - these medicines may irritate the stomach and make your condition worse. Your doctor or pharmacist may suggest other medicines you can take.

**Caffeine** - may irritate your stomach. Your doctor or pharmacist may advise you to limit the number of drinks that contain caffeine such as coffee, tea, cocoa or cola drinks.

**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.

**Weight** - losing some weight may help your condition.

**Smoking** - your doctor or pharmacist may advise you to stop smoking or at least cut down.

---

## Side effects

---

**All medicines have unwanted 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. Do not be alarmed by this list of possible side effects. You may not experience any of them.**

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

- Headache.
- Dizziness.
- Constipation.
- Diarrhoea.

These are the more common side effects of Famohexal. Mostly, these are mild and short-lived.

**If any of the following happen, stop taking Famohexal, 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.**
- **Hives or nettlerash (pinkish, itchy swellings on the skin).**
- **Yellowing of the skin and/or eyes, also called jaundice.**

**These are very serious side effects. You may need urgent medical attention or hospitalisation. All of these side effects are rare.**

**Tell your doctor if you notice any skin rash or itchiness.**

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

---

## After using Famohexal

---

### *Storage*

**Keep Famohexal in the original packaging until you need to take it. If you take the tablets out of the blister pack they may not keep well.**

**Store below 25°C in a dry place, out of the reach of children.**

### *Disposal*

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

---

## Product description

---

### *What Famohexal looks like*

Famohexal 20mg tablets: white, oblong, biconvex film-coated tablets with a break score on one side. They are available in blister packs of 60 tablets.

Famohexal 40mg tablets: white, oblong, biconvex film-coated tablets with a break score on one side. They are available in blister packs of 30 tablets.

### *Ingredients*

#### **Active ingredients**

Each Famohexal 20mg tablet contains 20mg famotidine as the active ingredient.

Each Famohexal 40mg tablet contains 40mg famotidine as the active ingredient.

### **Inactive ingredients**

As well as the active ingredient, Famohexal also contains some inactive ingredients. These are microcrystalline cellulose, pregelatinised maize starch, sodium starch glycollate type A, colloidal anhydrous silica, purified talc, magnesium stearate, lactose, hypromellose, titanium dioxide, and macrogol 4000.

### *Supplier*

Famohexal is supplied in Australia by:

Sandoz Pty Ltd  
Level 4, 100 Harris St  
Pyrmont NSW 2009

Tel: 1800 634 500

This leaflet was revised in October 2006.

### *Australian Register Number*

Famohexal 20mg tablets  
AUST R 94330 (blisters)  
Famohexal 40mg tablets:  
AUST R 94332 (blisters)