Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Pamacid.

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 Pamacid against the benefits expected 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 Pamacid is used for

Pamacid is used in the treatment of the following conditions:

Reflux disease

Also called reflux oesophagitis, this condition is caused by the washing back of food and acid from the stomach into the food pipe. A painful burning sensation occurs in the chest rising up to the throat (heartburn) and most often occurs after eating or at night.

Peptic ulcers

These ulcers usually cause pain and discomfort (indigestion) which is felt between the navel and the breast bone. 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 in the duodenum, which is the tube leading out of the stomach.

Pamacid is also used to help prevent the reoccurrence of duodenal ulcers and reflux disease.

Zollinger-Ellison syndrome

A rare condition where the stomach produces excessive amounts of acid, much more than in peptic ulcers and reflux disease.

Pamacid belongs to a group of medicines called histamine H2 antagonists or histamine H2 blockers. These medicines work by decreasing the amount of stomach acid produced, which in turn helps reduce the pain and also allows the ulcer and/or reflux disease to heal in most people.

Ask your doctor if you have any questions about why Pamacid has been prescribed for you.

Your doctor may have prescribed Pamacid for another reason.

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

There is no evidence that Pamacid is addictive.

Before you take Pamacid

When you must not take it

Do not take Pamacid if you are allergic to medicines containing famotidine or any other histamine H2 antagonist medicine or any of the ingredients listed at the end of this leaflet.

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

Do not take Pamacid if you are breastfeeding. Pamacid passes into breast milk and may affect your baby.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

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 plan to become pregnant or breastfeed.

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

Tell your doctor if you have any medical conditions, especially the following:

- kidney disease
- · chronic lung disease
- diabetes
- a weakened immune system or lowered resistance to infection, sometimes caused by certain diseases or treatments.

Your doctor may want to take special care if you have any of these conditions.

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

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 be affected by Pamacid, or may affect how well it works. Pamacid has not been shown to interfere with other medicines.

How to take Pamacid

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

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

Your doctor will tell you how many tablets you need to take each day and when to take them. This depends on the condition you are taking it for.

Peptic ulcers

The usual dosage for the treatment of peptic ulcers is one 40 mg tablet at night.

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

Reflux disease

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

Zollinger-Ellison syndrome

The dose depends on how much acid your stomach makes. Your doctor will decide how much you need to take.

People with kidney problems may require lower doses.

When to take it

Swallow the tablets with a glass of water.

Pamacid can be taken with or without food.

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 your tablets at about the same time each day.

This will help you remember when to take the tablets.

If you forget to take it

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 have any questions about this, check with your doctor or pharmacist.

How long to take it for

To treat a peptic ulcer, Pamacid is usually taken for 4 to 8 weeks. Your doctor will tell you how long to take the tablets.

Do not stop taking Pamacid, even if you feel better after a few days, unless advised by your doctor.

The ulcer may come back if you stop treatment too early.

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

Keep taking Pamacid for as long as your doctor recommends.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to the nearest hospital, if you think you or anyone else may have taken too much Pamacid. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are taking Pamacid

Things you must do

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

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

If you become pregnant while taking Pamacid, tell your doctor immediately.

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

Things you must not do

Do not use Pamacid to treat any other conditions unless your doctor tells you to.

Do not give Pamacid 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 Pamacid affects you.

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

Suggestions that may help your condition

Below are some self help measures which may help your condition. For more information talk to your doctor or pharmacist.

- Eating habits Try not to rush at meal times.
 Eat slowly and chew your food carefully. Try eating smaller, more frequent meals.
- Food avoid foods that cause you pain or discomfort
- Alcohol your doctor may advise you to limit your alcohol intake.
- Weight losing some weight may help your condition.
- Aspirin and many other medicines used to treat arthritis/period pain/headache - these 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 may advise you to limit the number of drinks which contain caffeine, such as coffee, tea, cocoa and cola drinks.
- Smoking your doctor 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 Pamacid.

Pamacid helps most people with ulcers or reflux disease but it may have unwanted side effects in some people.

All medicines have side 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.

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
- constipation
- diarrhoea.

These are generally mild side effects.

If any of the following more serious side effects occur, stop taking Pamacid 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
- pinkish, itchy swellings on the skin (hives or nettle rash)
- yellowing of the skin and/or eyes (jaundice)
- joint pain
- any severe skin reaction

• convulsions (very rare).

If you have any of these side effects, you may have an allergic reaction to Pamacid. You may need urgent medical attention or hospitalisation. These side effects are rare.

Tell your doctor if you notice anything that is making you feel unwell.

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

After taking Pamacid

Storage

Keep Pamacid 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 blister 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 $25^{\circ}\mathrm{C}.$

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

Do not leave Pamacid in the car or on window sills

Heat and dampness can destroy some medicines.

Disposa

If your doctor tells you to stop taking Pamacid, 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

Pamacid tablets are available in 2 strengths:

- Pamacid 20 white, film-coated, D-shaped tablet marked "G" on one side and "FD" over "20" on the other
- Pamacid 40 light brown, film-coated, scored, diamond-shaped tablet marked "G|G" on one side and "FD 40" on the other.

Each Pamacid 20 pack contains 60 tablets.

Each Pamacid 40 pack contains 30 tablets.

Ingredients

The active ingredient in Pamacid is famotidine.

Pamacid 20

Each Pamacid 20 tablet contains 20 mg of famotidine.

The tablets also contain the following inactive ingredients:

- pregelatinised maize starch
- microcrystalline cellulose
- purified talc
- magnesium stearate
- lactose
- hypromellose
- titanium dioxide (E171)
- glycerol triacetate.

Pamacid 40

Each Pamacid 40 tablet contains 40 mg of famotidine.

The tablets also contain the following inactive ingredients:

- pregelatinised maize starch
- microcrystalline cellulose
- purified talc
- magnesium stearate

- lactose
- hypromellose
- · glycerol triacetate
- iron oxide red CI77491 (E172)
- iron oxide yellow CI77492 (E172)
- titanium dioxide (E171).

The tablets are gluten free.

Supplier

Pamacid is supplied by:

Alphapharm Pty Limited (ABN 93 002 359 739) Level 1, 30 The Bond 30-34 Hickson Road

Millers Point NSW 2000 Phone: (02) 9298 3999 www.alphapharm.com.au

Medical Information Phone: 1800 028 365

Australian Registration Numbers:

Pamacid 20 - AUST R 82471 Pamacid 40 - AUST R 82470

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