

PEPCIDINE(R)

Famotidine

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about PEPCIDINE. 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 risks of you taking PEPCIDINE against the benefits they expect it will 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 need to read it again.

What PEPCIDINE is used for

PEPCIDINE 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:

PEPCIDINE 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.

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

Reflux disease:

PEPCIDINE 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:

PEPCIDINE 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.

PEPCIDINE belongs to a group of medicines called H₂-antagonists or H₂-blockers. PEPCIDINE 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.

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

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

PEPCIDINE is not addictive.

Before you take PEPCIDINE

When you must not take it

Do not take PEPCIDINE if:

* **you have an allergy to PEPCIDINE, or to any of the ingredients listed at the end of this leaflet**

Symptoms of an allergic reaction may include skin rash, itchiness, shortness of breath or swelling of the tongue or face.

* **you have an allergy to any other 'H₂-antagonist or H₂-blocker' medicines**

If you have had an allergic reaction to any of these before, you may be allergic to PEPCIDINE.

* **you are breast-feeding**

PEPCIDINE passes into breast milk and therefore there is a possibility that the breast-fed baby may be affected.

* **the packaging is torn or shows signs of tampering**

* **the expiry date on the pack has passed.**

If you take this medicine after the expiry date has passed, it may not work.

If you are not sure whether you should start taking PEPCIDINE, talk to your doctor.

Before you start to take it

Tell your doctor if:

1. you are pregnant, intend to

become pregnant, or plan to breast-feed

PEPCIDINE is not recommended for use during pregnancy. If there is a need to consider PEPCIDINE during your pregnancy, your doctor will discuss with you the benefits and risks of using it. PEPCIDINE passes into breast milk.

- 2. you have kidney disease or any other medical condition**
- 3. you have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes.**

If you have not told your doctor about any of the above, tell them before you take PEPCIDINE.

Taking other medicines

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

Some medicines may affect the way other medicines work. However, PEPCIDINE has not been shown to interfere with other medicines.

How to take PEPCIDINE

How much to take

Take PEPCIDINE only when prescribed by your doctor.

Your doctor will tell you how many tablets you need to take each day.

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 the dose.

If you have impaired kidney function, your doctor may lower your dose.

Carefully follow all directions given to you by your doctor.

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.

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 PEPCIDINE with food or not.

Swallow PEPCIDINE with a glass of water.

Take your PEPCIDINE at about the same time each day.

This will help you remember when to take the tablets.

How long to take it

For peptic ulcers, you will need to take PEPCIDINE for 4 to 8 weeks. Your doctor will tell you how long to take the tablets.

Do not stop taking PEPCIDINE 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 PEPCIDINE 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 PEPCIDINE for longer. Your doctor will let you know how long you need 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 it as soon as you remember, and then go back to taking your tablet(s) as you would normally. If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

Do not take a double dose to make up for the dose that 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 Poisons Information Centre (telephone 13 11 26) if you think that you or anyone else may have taken too much PEPCIDINE. Do this even if there are no signs of discomfort or poisoning.

While you are using PEPCIDINE

Things you must do

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

Things you must not do

Do not give PEPCIDINE 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 PEPCIDINE affects you.

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

PEPCIDINE 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 doctor may advise you to limit your alcohol intake.

* **Aspirin and many other medicines used to treat arthritis/period pain/ headache -**

these medicines may irritate the stomach and may 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 may advise you to stop smoking or at least cut down.

* **Weight -**

your doctor may suggest losing some weight to help your condition.

Side Effects

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

PEPCIDINE helps most people with ulcers or reflux disease, but it may have unwanted side effects in a few people. All medicines can 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.

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 that some people may get.

Rarely, more serious side effects may occur. If any of the following happen, stop taking PEPCIDINE 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
- * convulsions (very rare)

These may be some of the serious side effects. If you have some of these, you may have an allergic reaction to PEPCIDINE. You may need urgent medical attention or hospitalisation. These side effects are rare.

Also, tell your doctor if you notice skin rash or itchiness.

Other side effects not listed above may also occur in some patients. Tell your pharmacist or doctor if you notice any other effects.

Do not be alarmed by this list of possible side effects. They do not occur often and you are unlikely to experience any of them.

After using PEPCIDINE

Storage

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 PEPCIDINE in a cool dry place where the temperature stays below 30 degrees C. Do not store it or any other medicines in the bathroom or near a sink.

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

Heat and dampness can destroy some medicines.

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

Product description

What it looks like

PEPCIDINE comes in two types of tablets:

- * PEPCIDINE-M - beige coloured, rounded square-shaped tablet

with 'MSD 963' marked on one side

- * PEPCIDINE - tan coloured, rounded square-shaped tablet with 'MSD 964' marked on one side

A box of PEPCIDINE-M contains 60 tablets; a box of PEPCIDINE contains 30 tablets.

Ingredients

Active ingredient:

PEPCIDINE M - 20 mg famotidine per tablet

PEPCIDINE - 40 mg famotidine per tablet

Inactive ingredients:

- * maize starch
- * cellulose
- * magnesium stearate
- * talc
- * hypromellose
- * hydroxypropyl cellulose
- * titanium dioxide
- * iron oxide red CI77491
- * iron oxide yellow CI77492

PEPCIDINE does not contain gluten, lactose, sucrose, tartrazine or any other azo dyes.

Manufacturer

PEPCIDINE is made in Australia by:
Merck Sharp & Dohme (Australia)
Pty Limited
54-68 Ferndell Street
SOUTH GRANVILLE NSW 2142

This leaflet was prepared in February 2008.

IPC-PCD-MF-122006

Australian Register Numbers:

PEPCIDINE-M - AUST R 10506

PEPCIDINE - AUST R 10504

(R) Registered Trademark of Merck & Co., Inc. Whitehouse Station, N.J., U.S.A.