

PACKAGE LEAFLET: INFORMATION FOR THE USER

PEPCID[®] 20 mg Film-coated Tablets
PEPCID[®] 40 mg Film-coated Tablets
(famotidine)

Read all of this leaflet carefully before you start to take this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Pepcid is and what it is used for
2. Before you take Pepcid
3. How to take Pepcid
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1. What Pepcid is and what it is used for

Pepcid contains a medicine called famotidine (either 20 mg or 40 mg). This belongs to a group of medicines called 'H₂-blockers'. Pepcid works by lowering the amount of acid you produce in your stomach.

Pepcid is used for:

- preventing ulcers in your stomach (gastric ulcer) or the first part of your intestine (duodenal ulcer)
- healing ulcers and to give you relief from symptoms. Pepcid may also be used to lower the chance that your duodenal ulcer will come back
- treating 'gastro-oesophageal reflux disease' (GORD) caused by stomach acid and food from your stomach going back up into your food pipe (oesophagus), or for preventing the symptoms from coming back
- 'Zollinger-Ellison syndrome' where your stomach produces too much acid.

Talk to your doctor if you have any questions about this.

2. Before you take Pepcid

Do not take Pepcid if:

- you have ever had an allergic reaction to the active ingredient of this medicine or to any of the other ingredients (listed in section 6 below)
- you have ever had an allergic reaction to a similar medicine
- you are or think you may be pregnant
- you are planning to become pregnant
- you are breast-feeding.

Do not take Pepcid if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Pepcid.

Children

It is not known if this medicine is safe for use in children. Talk to your doctor about use in children.

Take special care with Pepcid

Check with your doctor or pharmacist before taking your medicine if you have kidney problems.

Your doctor may check your blood count and liver function, if you have been taking this medicine for a long time.

It is important that you do not suddenly stop taking Pepcid without talking to your doctor if you have had an ulcer for a long time.

Your doctor should check that your ulcer is not malignant before starting treatment.

Taking other medicines

Please tell your doctor if you are taking or have recently taken any other medicines, including those obtained without a prescription. In particular you should tell your doctor or pharmacist if you are taking any of the following medicines:

- probenecid, used for gout or arthritis caused by gout
- itraconazole or ketoconazole, used for fungal infections.
- Atazanavir, used for treatment of HIV infection
- antacids, used for treatment of heartburn or acid indigestion
- sucralfate, used for treatment of ulcers.

Pregnancy and breast-feeding

- you are or think you may be pregnant
- you are planning to become pregnant
- you are breast-feeding.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Some patients have experienced adverse reactions such as dizziness and headache while taking Pepcid. Do not drive or operate machinery until you see how Pepcid affects you and whether you experience these symptoms. (See 4. Possible side effects.)

3. How to take Pepcid

Taking this medicine

You should take this medicine by mouth. The number of tablets you take each day will depend upon your condition and whether you have kidney problems.

- Swallow the tablet with water
- Do not take more or less than your doctor has prescribed
- You should keep taking the tablets for as long as your doctor has asked, even though you may feel better very quickly.
- It is important that you do not stop taking the tablets without talking to your doctor.

The usual doses are:

For an ulcer

- **Treatment:** One 40 mg tablet at night, for 4 to 8 weeks. This may change depending on how you respond to the treatment.
- **Prevention:** One 20 mg tablet at night.

For 'gastro-oesophageal reflux disease' (GORD)

- **Prevention of mild symptoms:** One 20 mg tablet in the morning and one 20mg tablet at night.
- **Treatment of mild symptoms:** One 20 mg tablet in the morning and one 20mg tablet at night, for 6 to 12 weeks.
- **Treatment of more severe symptoms:** One 40 mg tablet in the morning and one 40 mg tablet at night, for 6 to 12 weeks.

For 'Zollinger-Ellison Syndrome'

- One 20 mg tablet every six hours.
- Some patients may need higher doses for this condition.

If you take more Pepcid than you should

- Please contact your doctor immediately.

If you forget to take Pepcid

- Do not take an extra dose. Take the normal amount of Pepcid the next time you are due to take a dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Pepcid can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

Frequencies are defined as: very common ($\geq 1/10$); common ($\geq 1/100$ to $< 1/10$); uncommon ($\geq 1/1,000$ to $< 1/100$); rare ($\geq 1/10,000$ to $< 1/1,000$) and very rare ($< 1/10,000$), not known (cannot be estimated from the available data).

Common

- Headache, dizziness
- Constipation, diarrhoea

Uncommon

If you have an allergic reaction, stop taking Pepcid and see a doctor straight away. The signs may include:

- swelling of your hands, face, lips, tongue or throat (with difficulty in breathing or swallowing)

- hives
- dry mouth or changes in taste
- feeling sick, vomiting
- mild stomach pain or bloating
- flatulence
- rash
- loss of appetite
- feeling tired
- itching

Very rare

- allergic reactions (swelling of the face, lips, mouth, tongue or throat which may cause difficulty swallowing or breathing).
- feeling tired, depressed, anxious, agitated, confused or seeing or hearing things that are not really there (hallucinations) and disorientation. These usually go away after stopping Pepcid
- difficulty sleeping
- Fits (particularly in people with kidney problems)
- tingling feeling or numbness
- less desire to have sex
- itching, blistering of your skin, mouth, eyes and genitals known as Stevens-Johnson Syndrome
- slow or irregular heart beat
- pneumonia
- painful joints, muscle cramps
- yellowing of your skin or whites of your eyes, caused by liver or blood problems (jaundice)
- changes in liver enzyme tests (usually seen in a blood test)
- lowered blood-cell counts and worsening liver problems (usually seen in a blood test), although these may not have been caused by Pepcid.
- being unable to have an erection (impotence)
- hair loss
- Certain changes in the electrical activity of the heart that can be seen on a heart tracing or ECG. Although very rare, these can sometimes be serious (particularly in people with kidney problems)

Not known

- breast enlargement in men (this usually goes away after stopping Pepcid).

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet please tell your doctor or pharmacist. It will help if you make a note of what happened, when it started and how long it lasted.

5. How to store Pepcid

Keep your tablets out of the reach and sight of children.

Do not store your tablets above 25°C. Keep them in the original package.

If you have been given a calendar pack, do not remove the tablets from the blister until you are ready to take the medicine.

Do not use Pepcid after the expiry date which is stated on the carton after the letters EXP. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What Pepcid contains

- The active ingredient is famotidine. Pepcid tablets are available in two strengths:
 - The square-shaped, round-cornered, film-coated, beige-coloured tablet marked 'MSD 963' on one side and plain on the other contain 20 mg famotidine.
 - The square-shaped, round-cornered, film-coated, brown-coloured tablet marked 'MSD964' on one side and plain on the other contain 40 mg famotidine.
- The other ingredients are Carnauba wax (E903), magnesium stearate (E572), pregelatinised maize starch, hypolose (E463), hypromellose (E464), red iron oxide (E172), yellow iron oxide (E172), talc, titanium dioxide (E171), microcrystalline cellulose (E460).

Pepcid tablets are available in calendar blister packs containing 28 tablets.

Marketing Authorisation Holder and Manufacturer

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This leaflet was last approved in xx/xxxx

This leaflet gives you some important patient information about Pepcid. If you have questions after you read it ask your doctor or pharmacist, who will give you further information.

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