

Pepcid[®]AC

10mg film-coated tablets

**Famotidine
Acid Control**

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4. ▶
- You must talk to a doctor if you do not feel better or if you feel worse after 14 days.

What is in this leaflet:

1. What Pepcid AC is and what it is used for
2. What you need to know before you take Pepcid AC
3. How to take Pepcid AC
4. Possible side effects
5. How to store Pepcid AC
6. Contents of the pack and other information

1 What Pepcid AC is and what it is used for

Pepcid AC tablets are for the short-term symptomatic relief of heartburn, indigestion (dyspepsia) and excess acid. They can prevent these symptoms when they follow a meal or beverage (drink) known to trigger them. Pepcid AC taken before the evening meal can also prevent night-time symptoms which disturb sleep when this is associated with food or drink.

Pepcid AC provides relief from the symptoms of heartburn and indigestion with just one small tablet. It has been clinically proven to control excess stomach acid for nine hours throughout the day and for 12 hours throughout the night. The active ingredient in your medicine is famotidine. This belongs to a group of medicines known as "H2 blockers". Unlike antacids which neutralise acids, famotidine controls the production of excess acid and treats the cause of pain and discomfort.

You must talk to a doctor if you do not feel better or if you feel worse after 14 days.

2 What you need to know before you take Pepcid AC

This medicine is suitable for most people, but a few people should not use it. If you are in any doubt, talk to your doctor or pharmacist.

Do not take this medicine....

- If you are allergic to famotidine or any other ingredient of this medicine (listed in section 6).
- If you are allergic to other H2 blockers (medicines which control the production of excess stomach acid).

Warnings and precautions

Talk to your doctor or pharmacist before taking Pepcid AC ...

- If you have **lost weight unintentionally and / or**
- If you are **over 50 years old and have indigestion for the first time.**

Your doctor will want to exclude the possibility of cancer before you start taking this medicine.

- If you have **kidney problems.**

Patients should stop use and consult a physician if symptoms persist or worsen, or if they experience dysphagia (difficulty swallowing), odynophagia (pain on swallowing), severe vomiting, melaina (black stools), choking or chest pain.

Children and adolescents

Pepcid AC must not be given to children below 16 years.

Other medicines and Pepcid AC

Talk to your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Pepcid AC may affect or be affected by some other medicines. For example:

- Other antacids
- Sucralfate (for stomach ulcers)
- Antifungals (such as ketoconazole and itraconazole)
- Probenecid (for gout)
- Ulipristal (for emergency contraception)
- Cyanocobalamin (Vitamin B12)
- Tyrosine kinase inhibitors (anticancer drugs, excluding vandetanib and imatinib)
- Atazanavir and rilpivirine (used for HIV)
- Calcium carbonate, when used as a medicine for high blood phosphate levels (hyperphosphataemia) in patients on dialysis.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

If you feel dizzy after taking Pepcid AC, you should not drive or use machines.

3 How to take Pepcid AC

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

Check with your doctor or pharmacist if you are not sure. For oral use only.

Do not take more than the stated dose shown in the table below.

Adults and children over 16 years

Age	Dose
Adults and children over 16 years	Daytime dose: Swallow 1 tablet to relieve the symptoms of heartburn, indigestion or excess acid. You can prevent these symptoms when they are known to be associated with food and drink by taking 1 tablet 15 minutes before eating. Nighttime dose: Swallow 1 tablet within one hour before the evening meal for prevention of nighttime symptoms.

- Tablets should be swallowed **WHOLE** with a glass of water, **NOT** chewed.

- If symptoms persist for longer than two weeks, or worsen you must see a doctor or pharmacist.
- Do not take more than 2 tablets in 24 hours.

turn over ▶

Use in children and adolescents

This medicine is not recommended for children under 16 years of age.

If you take more Pepcid AC than you should

If anyone takes too much Pepcid AC, contact your doctor taking this leaflet and pack with you.

If you forget to take Pepcid AC

You should only take this medicine as required following the dosage instructions above carefully. If you forget to take a dose, take a dose as soon as you remember. Do not take a double dose to make up for a forgotten 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 AC can cause side effects, although not everybody gets them.

If you experience any of the following, STOP taking the medicine and seek immediate medical help:

- Serious allergic reaction e.g., swelling of the face, tongue or throat which may cause difficulty in breathing.
- Severe extensive skin damage (blistering and peeling of skin).
- Unexplained bruising, bleeding or getting more infections which may be due to lowering of blood cell counts.

Other effects which may occur include:

Common (may affect up to 1 in 10 people):

- Headache
- Dizziness
- Constipation or diarrhoea

Uncommon (may affect up to 1 in 100 people):

- Decrease or loss of appetite
- Dry mouth or changes in taste
- Stomach discomfort, pain, bloating or flatulence
- Nausea or vomiting
- Unusual weakness or tiredness
- Rash or itching

Rare (may affect 1 in 1,000 people):

- Drowsiness
- Liver disorder
- Increased breast size in men
- Generally feeling unwell

Very rare (may affect up to 1 in 10,000 people):

- Feeling agitated, anxious, confused or disorientated
- Depression
- Hallucinations
- Seizures
- Difficulty sleeping
- Impotence or decreased sex drive
- Joint pain
- Pins and needles or muscle spasms
- Mental disorder
- Hair loss
- Chest discomfort

■ Heart block

- Jaundice (yellowing of eyes or skin)
- Lung disease (thickening of tissues between the air sacs of the lungs).

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side-effects directly via HPRA Pharmacovigilance, website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Pepcid AC

Store in the original package in order to protect from moisture.

Keep this medicine out of the sight and reach of children.

Do not use your medicine after the date shown as the expiry date on the packaging. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6 Contents of the pack and other information

What Pepcid AC contains

The active substance in Pepcid AC is: 10mg of famotidine.

Other ingredients are: pregelatinised starch, cellulose microcrystalline, talc, magnesium stearate, hydroxypropyl methylcellulose, hydroxypropylcellulose, titanium dioxide (E171), carnauba wax, red ferric oxide (E172).

What Pepcid AC looks like and contents of the pack

Pepcid AC are pale-rose, rounded-square, film-coated tablets with FA10 engraved on one side.

The pack sizes are 6, 12 and 18 tablets. Not all pack sizes may be marketed.

Marketing authorisation holder:

JNTL Consumer Health I (Ireland) Ltd.
Block 5, High Street, Tallaght, Dublin 24, Ireland.

Manufacturer:

Janssen-Cilag SpA, Via C Janssen, Borgo San Michele, 04100 Latina, Italy.

This leaflet was revised March 2024.

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