

PACKAGE LEAFLET: INFORMATION FOR THE USER

Pepcid Duo Chewable tablets

Famotidine 10mg, magnesium hydroxide 165mg, calcium carbonate 800mg

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 2 weeks.

What is in this leaflet?

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

1. What Pepcid Duo is and what it is used for

Pepcid Duo is used for the short-term treatment of the symptoms of heartburn and acid indigestion in adults and adolescents of 16 years & over.

Pepcid Duo contains three active substances:

- Famotidine is a medicine called a 'H2 Antagonist (blocker)'. It reduces acid production in your stomach.
- Magnesium hydroxide and calcium carbonate are 'antacids'. They neutralise the acid in your stomach.

2. What you need to know before you take Pepcid Duo

Do not take Pepcid Duo:

- if you are allergic to famotidine, magnesium hydroxide, calcium carbonate or any of the other ingredients of this medicine (listed in section 6)
- if you have severe kidney problems
- if you are allergic to other H2 Antagonist (medicines which controls the production of excess stomach acid)

Warnings and precautions

Talk to your doctor or pharmacist before taking Pepcid Duo if you have:

- Indigestion and have also lost weight involuntarily
- Stomach pain which does not go away
- Indigestion for the first time, or if your symptoms have recently changed
- Too much calcium in your blood
- Too much magnesium in your blood
- Too little phosphorus in your blood
- Too much calcium in your urine, or a history of kidney stones
- Kidney or liver problems

If you use Pepcid Duo for a long time, the levels of calcium in your blood may go up. This is more likely if you are also taking other medicines that contain calcium and/or vitamin D. If this happens, your kidneys could be affected.

Stop using this medicine and consult a doctor if you have:

- New symptoms
- Difficulty swallowing
- Pain on swallowing
- Severe vomiting
- Black stools
- Choking or chest pain

If your symptoms persist or worsen after 2 weeks of treatment, do not continue treatment and consult your doctor.

Children and adolescents

Do not give this medicine to children under the age of 16 years because there is no data to show safety and efficacy in this age group.

Other medicines and Pepcid Duo

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

- Calcium carbonate, when used as a medicine for high blood phosphate levels (hyperphosphataemia) in patients on dialysis.

Pepcid Duo may decrease the effects of other medicines. For this reason, do not take Pepcid Duo within two hours of taking any other medicine.

These medicines include:

- antibiotics (for bacterial infections)
- beta-blocking agents (for blood pressure)
- bisphosphonates (for osteoporosis)
- glucocorticosteroids (for inflammatory conditions)
- rilpridine, atazanavir or integrase inhibitors such as raltegravir, dolutegravir, elvitegravir (for HIV infection)
- phenothiazine neuroleptics and sulpiride (for psychosis/schizophrenia)
- thyroid hormones (replaces lack of or reduced production of thyroid hormone)
- salicylates and diflunisal (for fever or pain)
- chloroquine and proguanil (for malaria)
- digoxin (for heart conditions)
- estramustine (for prostate cancer)
- fexofenadine (for allergy symptoms)
- fluorine
- indomethacin (NSAID for pain/inflammation)
- iron or zinc or dietary supplements containing iron or zinc
- ledipasvir phosphore (for hepatitis C)
- rosuvastatin (a statin)
- strontium (for osteoporosis)
- sodium and calcium polystyrene sulphonate resins for the treatment of increased potassium levels in the blood
- teriflunomide (for multiple sclerosis)
- thiazide diuretics (for high blood pressure)
- cyanocobalamin (for vitamin B12 deficiency)
- most of tyrosine kinase inhibitors such as dasatinib, erlotinib, gefitinib, pazopanib (medicines used to treat cancer)
- ketoconazole, itraconazole, posaconazole (for prevention and treatment of some fungal infections)
- ulipristal (for emergency contraception)

Pepcid Duo with food and drink

Not applicable.

Pregnancy, breast-feeding and fertility

If you are pregnant, think you may be pregnant or are planning to have a baby, do not take Pepcid Duo.

If you are breast-feeding, ask your doctor for advice before taking this medicine, he will decide whether to discontinue breastfeeding or to discontinue/abstain from this medicine.

Driving and using machines

Pepcid Duo is not expected to affect your ability to drive or operate machinery. However, if dizziness or drowsiness appears, you should not drive or use machines.

Pepcid Duo contains lactose, glucose and benzyl alcohol

Lactose and glucose: If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

This medicine contains 0.0002 mg benzyl alcohol in each tablet. Benzyl alcohol may cause allergic reactions. If you have liver or kidney disease or if you are breastfeeding, ask your doctor for advice before taking this medicine. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called "metabolic acidosis").

3. How to take Pepcid Duo

Always take this medicine exactly as described in this leaflet or as your pharmacist has told you. Check with your pharmacist if you are not sure.

Adults & adolescents 16 years & over:

- When you get heartburn or indigestion, chew one tablet thoroughly.
Drink a glass of water, if possible, to wash the tablet down.
- Do not take more than 2 tablets per day.
- Do not take for more than 2 weeks (See also section 2).

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

If you take more Pepcid Duo than you should

Ask your doctor or pharmacist for advice.

If you forget to take Pepcid Duo

Do not take a double dose to make up for a forgotten dose.

If you stop taking Pepcid Duo

Not applicable.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

You should **STOP** taking Pepcid Duo and see your doctor immediately if you experience symptoms of a serious allergic reaction, such as:

- swelling of the face, tongue or throat, which may cause difficulty in swallowing; hives and breathing difficulties (not known – frequency cannot be estimated from the available data)
- serious allergic reaction which causes difficulty in breathing or dizziness (not known - frequency cannot be estimated from the available data)
- severe extensive skin damage (which may start with painful red areas, then large blisters and ends with peeling of layers of skin) (very rare)

The following side effects have also been reported with Pepcid Duo:

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

- Headache

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

- Nausea
- Vomiting
- Dizziness
- Belching
- Pins and needles

- Diarrhoea
- Flatulence
- Dry mouth
- Bloating stomach
- Nervousness
- Indigestion
- Thirst
- Stomach ache
- Sore throat
- Change in the way things taste
- Distended stomach

Not known (frequency cannot be estimated from the available data):

- Rash
- Itching
- Sleepiness
- Hives
- Unusual tiredness or weakness
- Loss of energy

There have been very rare reports (see below) in people taking higher doses of famotidine (one of the active substances in Pepcid Duo).

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

- Liver disorders or abnormal liver function results
- Nervous system disorders such as hallucinations, confusion, difficulty sleeping, fits, drowsiness, agitation and depression
- Blood disorders such as depleted/low platelets and/or red or white blood cells
A reduction in the number of white blood cells may decrease your resistance to infection. Therefore, if you experience an infection with symptoms such as fever and serious deterioration of your general condition, or fever with local infection symptoms such as sore throat/pharynx/mouth or urinary problems, you should see your doctor immediately. A blood test will be taken to check possible reduction of white blood cells.
- Musculoskeletal disorders such as muscle cramps
- Impotence, reduced sex drive and breast tenderness
- Alopecia (hair loss)
- Generally feeling unwell

The other two active substances in Pepcid Duo (magnesium hydroxide and calcium carbonate) can cause change in stool frequency and consistency, bloating and fullness.

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 Duo

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the blister and carton. The expiry date refers to the last day of that month.
- Do not store this medicine above 30°C.
- 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 Duo contains

The active substances in Pepcid Duo are famotidine (10 mg), magnesium hydroxide (165 mg) and calcium carbonate (800 mg). The other ingredients are glucose, sucralose (E955), lactose,

crospovidone, cellulose acetate, maltodextrin (contains glucose), magnesium stearate (E572), hypromellose (E464), hydroxypropyl cellulose (E463), cool Spearmint Flavour (contains benzyl alcohol), Prosweet flavour, FD&C Blue No.1, Aluminum Lake, Certified and ferric oxide (yellow) (E172).

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What Pepcid Duo looks like, and contents of the pack

Pepcid Duo is a green, chewable tablet marked with a 'P'.
Each pack contains 2, 6, 12, 18 or 24 tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing authorisation holder:
JNTL Consumer Health I (Ireland) Ltd. Block 5, High Street, Tallaght, Dublin 24, Ireland.
Manufacturer:
Janssen Cilag S.P.A, Via C. Janssen, Latina, 04100, Italy.
Or
JNTL Consumer Health (France) SAS, Domaine de Maigremont, 27100 Val de Reuil, France.

This medicinal product is authorised in the Member States of the EEA under the following names:

Ireland: PEPCID DUO chewable tablets
Finland: PEPCID DUO purutabletti
Norway: PEPCIDDUO tyggetablett
Sweden: PEPCID DUO tuggablett

This leaflet was last revised in

Health education advice

Changes of diet (acidic or spicy foods, alcohol, etc.) or certain medicines (aspirin, anti-inflammatory drugs, etc.) can cause stomach pain, heartburn, and acid indigestion. Do not hesitate to ask your doctor or pharmacist for advice.

These following rules should help you to avoid the symptoms:

- Avoid large, fatty meals
- Avoid certain foods such as chocolate, spices, peppers, citrus juice, fizzy drinks
- Vary your diet
- Lose any excess weight
- Avoid hard exercise just after a meal
- Do not smoke and reduce your alcohol consumption

Your pharmacist and your doctor know about medicines. Do not hesitate to ask them for advice.