



Gastroprotect 10 mg /165 mg /800 mg chewable tablets

(Famotidine/ Magnesium hydroxide/ Calcium carbonate)

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 doctor or 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.
- You must talk to a doctor if you do not feel better or if you feel worse after 15 days.

What is in this leaflet

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

1. What Gastroprotect is and what it is used for

The drug product Gastroprotect is a combination of three active substances: famotidine, used to reduce gastric acid, and two widely used antacid agents (reducing gastric acid) – calcium carbonate and magnesium hydroxide. Gastroprotect is intended to relieve the symptoms of indigestion or gastric hyperacidity. The combination product Gastroprotect acts in two ways: calcium carbonate and magnesium hydroxide work by rapidly neutralising the excess acids already produced in the stomach whereas famotidine exerts a more continuous effect by reducing acidity for 12 hours preventing gastric acid secretion. The optimum combination of these two actions effectively maintains the normal acidity in the stomach allowing the recovery of the irritated and inflamed stomach lining.

Gastroprotect is used for short-term symptomatic treatment of irritation and inflammation of the oesophagus, stomach and duodenum, and functional secretory stomach disorders:

- to relieve stomach discomfort: acid indigestion, burning sensation, pain, heaviness in the stomach, bloating, nausea, etc. as a result of excess gastric acid production, in case of acute and chronic gastritis, stomach ulcers or ulcers of the upper part of the intestine (duodenal ulcers), acid reflux including reflux caused by poor nutrition, alcohol abuse and tobacco smoking, or some medications;
- hyperacidity of gastric juice;
- indigestion (non ulcer dyspepsia), to relieve gastrointestinal tract action

2. What you need to know before you take Gastroprotect

Do not take Gastroprotect:

- 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 are allergic to other acid-reducing drugs (such as ranitidine, cimetidine, etc.);
- if you suffer from renal failure;
- children and adolescents under the age of 16 years should not take Gastroprotect;
- if you are pregnant or breast-feeding.

Warnings and precautions

Talk to your doctor or pharmacist before taking Gastroprotect.

Some symptoms may indicate a serious problem, therefore you should seek immediate medical advice if you have:

- chest or shoulder pain and superficial breathing, sweating, pain spreading to the arms, neck and shoulders, pain in the jaw (especially with trouble breathing);
- difficult and painful swallowing;

- dizziness, nausea, vomiting;
- vomit that is bloody or looks like coffee grounds.
- bleeding or blood in the stools, black stools,
- heartburn for longer than 3 months;
- heartburn combined with pain, dizziness, sweating and lightheadedness;
- persistent stomach pain;
- if you are over the age of 40 years, and have recently experienced new or changed symptoms of indigestion and heartburn;
- unexplained weight loss;

Gastroprotect should be used with caution

Talk to your doctor if any of these apply to you:

- if you have a gastric or duodenal ulcer, a malignancy should be ruled out;
- if you use other medications for the treatment of stomach hyperacidity;
- if you take non-steroidal anti-inflammatory drugs;
- if you have had an ulcer or complications in the past;
- if you have a confirmed hypercalcaemia since the product contains calcium;
- if you have a confirmed hypophosphatemia since the product may deteriorate this condition;
- if you have a confirmed hypercalciuria or have had kidney or urinary tract stones;
- if you have renal impairment, the product should be administered under medical supervision only, and the serum levels of calcium and magnesium should be monitored;
- in case of impaired hepatic or renal function, Gastroprotect should be used with caution;
- a long-term use, especially during treatment with other calcium-containing drugs and/or vitamin D-containing drugs, would put you at risk of having elevated levels of calcium in the blood with subsequent development of renal failure.

If the symptoms do not disappear after 15-day uninterrupted treatment, or if they get worse, you should talk to a doctor.

Children and adolescents

Children and adolescents under the age of 16 years should not take Gastroprotect.

Other medicines and Gastroprotect

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

If you are taking this medicine under control of your doctor, your doctor or pharmacist will be aware of all possible drug interactions, and will inform you of them. Do not start or stop taking a medicine, or change the dose of any medicine before talking to your doctor or pharmacist.

As a precaution, it is recommended to take Gastroprotect separately, at least two hours after taking other medicines, and at least four hours after taking quinolone antibiotic.

Before using this medicine, tell your doctor or pharmacist about all the medicines you are taking, with or without prescription, or herbal products, particularly if you are taking any of the following: amphetamines, atazanavir, antifungal agents (such as itraconazole, ketoconazole), bisphosphonates (e.g. alendronate), dasatinib, tetracycline antibiotics (e.g. doxycycline, tetracycline), quinolone antibiotics (e.g. ciprofloxacin, levofloxacin), medicines for treatment of thyroid disorders (e.g. levothyroxin), calcium channel blockers (e.g. diltiazem, verapamil), quinidine, delavirdine, digoxin, sodium polystyrene sulfonate, phosphorus supplements (e.g. potassium phosphate).

Check what is in the medications you are taking as they may contain aspirin or aspirin-like non-steroidal anti-inflammatory drugs (e.g. ibuprofen, naproxen) which may cause stomach irritation. Ask your doctor about the

safe use of these medicines.

The use of low-dose aspirin prescribed by your doctor to prevent heart attack or stroke (usually at a dose of 81 ÷ 125 mg daily) should not be discontinued.

Gastroprotect and famotidine-like acid blockers (e.g. cimetidine, ranitidine) should not be administered at the same time.

Not all possible drug interactions are listed in this leaflet. That is why, before using this product, inform your doctor or pharmacist about all products you are using.

For further information please ask your pharmacist or doctor before you start taking this medicine.

Pregnancy, breast-feeding and fertility

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. He should consider the benefit and risks of treatment with the combination product Gastroprotect.

Famotidine may pass into breast milk in small amounts. Magnesium salts may also pass into breast milk causing diarrhoea in newborn babies. For this reason, it is recommended for mothers to stop breastfeeding while they are using this medicine.

Driving and using machines

Due to a possible occurrence of dizziness, some potentially hazardous activities such as driving and using machines should be avoided.

3. How to use Gastroprotect

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.

The recommended dose is:

For adults and adolescents over the age of 16 years.

To relieve the symptoms, chew completely one table. Do not swallow the chewable tablet whole.

To prevent heartburn, chew one tablet 15 to 60 minutes before taking foods or beverages that cause indigestion.

Do not exceed the daily dose of two chewable tablets.

Treatment duration is 2 weeks (see section 2 :Before you take Gastroprotect); do not take this medicine for longer than two weeks.

If you take more Gastroprotect than you should

Seek medical advice if you have taken more than the recommended dose.

If you forget to take a dose

If you regularly take Gastroprotect but miss a dose at the usual time, take the missed chewable tablet as soon as you remember.

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

4. Possible side effects

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

The side effects of Gastroprotect chewable tablets are rare. They are usually mild, resolve quickly and are reversible when product administration is discontinued.

The most commonly observed adverse drug reactions are headache, nausea and diarrhoea.

The frequency of the adverse drug reactions is classified as follows:

Very common (more than 1/10 treated patients); Common (from 1 to 10/100 patients); Uncommon (from 1 to 10/1 000 patients), Rare (from 1 to 10/10 000 patients); Very rare (less than 1/10 000); Unknown frequency (cannot be estimated from the available data).

Nervous system disorders:

Common: headache;

Uncommon: restlessness, dizziness;

Gastrointestinal tract:

Uncommon: nausea, diarrhoea, bloating caused by gas, dyspepsia, belching, dry mouth, thirst.

Musculoskeletal, connective tissue and bone disorders:

Uncommon: numbness, tingling (pins and needles) in hands and feet (paraesthesia)

Other disorders:

Uncommon: abdominal distension, abdominal pain, taste perversion.

Some adverse effects have been reported in isolated cases

With unknown frequency:

- **Skin:** skin rash, itching, urticaria, and with other H2-antagonists: severe condition with skin blisters (toxic epidermal necrolysis).
- **Hypersensitivity:** severe allergic reaction causing difficulty breathing or dizziness (anaphylaxis), severe allergic reaction causing swelling of the face or throat (angioedema), difficulty breathing or wheezing (bronchospasm).
- **Hepatic diseases** including hepatic cholestasis (impaired flow of bile) and relative changes in the blood tests showing changes in liver functioning (increase in serum transaminases), gamma-GT, alkaline phosphatase and bilirubin.
- **Neurological disorders:** deceptive perceptions (hallucinations), confusion, insomnia, seizures, somnolence, anxiety, depression. These disorders are reversible upon treatment discontinuation
- **Blood diseases** such as low platelet count with increased risk of bleeding or bruising (thrombocytopenia), low white blood cell count which increases the potential risk of infection (leukopenia), severe reduction in the number of white blood cells with increased risk of infection (agranulocytosis) and severe reduction in the number of all blood cells which may lead to weakness, bruising or increased risk of infection (pancytopenia).
- **Musculoskeletal disorders:** muscle cramps
- **Other disorders:** e.g. impotence, decreased libido

Antacid-containing drug products such as magnesium and calcium, may precipitate changes in stool frequency and consistency, bloating and feeling of fullness.

If you notice any of the side effects listed above, please inform your doctor.

Reporting of suspected side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system.

By reporting side effects you can contribute to providing more information on the safety of this medicine.

5. How to store Gastroprotect

Store below 30°C.

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

Store in the original packaging.

Do not use this medicine after the expiry date which is stated on the carton. 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 Gastroprotect contains

- The active substances are 10 mg famotidine, 165 mg magnesium hydroxide and 800 mg calcium carbonate.
- The other ingredients are: dextrates, sodium starch glycolate, sodium cyclamate, peppermint flavour, magnesium stearate, pre-gelatinised starch and maize starch.

What Gastroprotect looks like and contents of the pack

The chewable tablets are white or almost white, round, flat with facet. One, two, three or four PVC/Al or PVDC/Al blisters x 6 chewable tablets (1 x 6; 2 x 6; 3 x 6; 4 x 6) and one or two PVC/Al or PVDC/Al blisters x 12 chewable tablets (1 x 12; 2 x 12) placed in a carton box with a package leaflet: Information for the user.

Marketing Authorisation Holder and Manufacturer

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