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1.5.3 Patient Information Leaflet (PIL)

**Package leaflet: Information for the patient
GASTRICID chewable tablet**

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

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- You must contact a doctor if your symptoms worsen or do not improve after 2 weeks.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this package leaflet:

1. WHAT GASTRICID IS AND WHAT IT IS USED FOR
2. BEFORE YOU TAKE GASTRICID
3. HOW TO TAKE GASTRICID
4. POSSIBLE SIDE EFFECTS
5. HOW TO STORE GASTRICID
6. CONTENT OF THE PACK AND OTHER INFORMATION

1. WHAT GASTRICID IS AND WHAT IT IS USED FOR

This medicine is indicated for the short term symptomatic treatment of heartburn or acid regurgitations in adults and adolescents from 16 years old.

Gastricid is a combination of three active substances:

- Famotidine, H₂-receptors antagonist, reducing the production of acid in the stomach.
- Magnesium hydroxide and calcium carbonate, antacids, neutralising the acidity in the stomach.

2. BEFORE YOU TAKE GASTRICID

Do not take GASTRICID:

- If you are allergic to famotidine, magnesium hydroxide, calcium carbonate or any other component of this medicine.
- If you have severe kidney or hepatic disorders.
- If you are allergic to other H₂ receptors antagonists (medicines controlling the excessive production of acid in the stomach).

Warnings and precautions:

Talk to your doctor or pharmacist before taking GASTRICID if you have

- digestion disorders associated with involuntary weight loss;
- persisting abdominal discomfort;
- digestive troubles occurring for the first time or if these symptoms have recently changed;
- excess of calcium in the blood;
- phosphorus deficiency in the blood;
- excess of calcium in the urines, or if you have history of kidney stones;
- kidney or liver disease.

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If you take GASTRICID for a long time, particularly together with other drugs containing calcium and/or vitamin D, too much calcium in your blood may lead to alter your kidney function.

Stop taking this medicine and talk to your doctor if you have:

- new symptoms
- difficulty swallowing
- pains when swallowing
- significant vomiting
- black stools
- suffocation feeling or chest pain.

If symptoms persist or get worse after two weeks of treatment, stop taking the medicine and talk to your doctor.

Children and adolescents

Do not give this medicine to children under 16 years of age because there is no data demonstrating its safety and efficiency in this age group.

Other medicines and GASTRICID

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

The two antacids contained in GASTRICID might stop the absorption of other medicines. For this reason, respect a 2 hours-interval between the intake of GASTRICID and any other medicine. These medicines include:

- antibiotics (against bacterial infections)
- beta blocking agents (for arterial hypertension)
- bisphosphonates (against osteoporosis)
- integrase inhibitors (against inflammatory disease)
- phenothiazine and sultopride neuroleptics (against psychosis and schizophrenia)
- thyroid hormones
- salicylates and diflunisal (against fever and pains)
- chloroquine and proguanil (against malaria)
- digoxin (against heart diseases)
- estramustine (against prostate cancer)
- fexofenadine (for allergy symptoms)
- fluoride
- indomethacin (NSAID against pains/inflammation)
- iron
- ledipasvir, phosphorus (against hepatitis C)
- roxuvastatin (a statin)
- strontium
- sulfonated or calcium polystyrene resins
- teriflunomide (against multiple sclerosis)

Famotidine in GASTRICID might reduce the absorption of your body of atazanavir and rilpivirine (against HIV), of cyanocobalamin (against vitamin B12 deficiency) and of most of tyrosine kinase inhibitor (against cancer). The association of famotidine and antacids might

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decrease the absorption of your body of azole antifungals (ketoconazole, itraconazole, posaconazole) and of ulipristal (in case of emergency contraception).

GASTRICID contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. Each tablet contains 727.30 mg lactose monohydrate.

Pregnancy and Breastfeeding:

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, do not take GASTRICID.

if you are breast-feeding, ask your doctor before taking this medicine, he will decide if you can continue breast-feeding or if you should stop/refrain from taking this medicine.

Driving vehicles and use of machines

No effect on driving vehicles or operating machines is expected, however, do not drive or operate machines if you experience dizziness.

3. HOW TO TAKE GASTRICID

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

Adults (from 16 years old)

- If heartburns or digestion disorders occur, chew a full tablet. Swallow with a glass of water preferably.
- Do not take more than 2 tablets per day
- Do not exceed 2 weeks of treatment.

If you have taken more GASTRICID tablets than you should:

Contact immediately your doctor or pharmacist.

If you forget to take GASTRICID

Do not take double doses to make up for the forgotten dose.

4. POSSIBLE SIDE EFFECTS

Like all medicines, GASTRICID can cause side effects, although not everybody gets them. You must **STOP** taking GASTRICID and consult your doctor immediately if you have the symptoms of a serious allergic reaction, as:

- swollen face, tongue or throat, that may make it difficult to breathe; urticaria and difficulty breathing (unknown – cannot be estimated from the available data).
- Allergic reaction that can cause difficulty breathing or dizziness (unknown – cannot be estimated from the available data).
- severe and spread skin damages (that can start with painful red areas, then wide blisters and finally peeling of the superficial layer of the skin) (very rare).

The following side effects have been reported with GASTRICID:

Common (might affect up to 1 patient out of 10):

- Headaches

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Uncommon (might affect up to 1 patient out of 100):

- Nausea
- Dizziness
- Burping
- Tingling sensation
- Diarrhoea
- Wind
- Bloating
- Nervousness
- Digestion disorders
- Thirst
- Stomach aches
- Sore throat
- Taste perversion
- Distended stomach

Unknown (the frequency cannot be estimated based on the available data):

- Skin rash
- Itchiness
- Somnolence
- Urticaria
- Tiredness or unusual weakness
- Loss of energy

There were only rare declarations (see below) in patients taking high doses of famotidine (one of the active substances of GASTRICID).

Very rare (might affect up to 1 patient out of 10,000):

- Liver disorders or abnormal results for liver function tests.
- Nervous system disorders, as hallucinations, confusion, sleeping disturbances, seizures, somnolence, agitation and depression.
- Blood disorders as decrease or depletion of platelets and/or red or white blood cells levels. A reduction in the white blood cells count might decrease your resistance to infections. Hence, if you have an infection with symptoms as fever and a serious deterioration of your general health status, or fever with symptoms of local infection as sore throat, pharynx or mouth or urinary disorders, you should immediately talk to your doctor. A blood test will be performed in order to monitor the potential reduction in white cells count.
- Musculoskeletal disorders as muscle cramps.
- Impotency, decreased libido and breast tenderness.
- Alopecia (hair loss).
- Generalised sensation of malaise.

The two other active ingredients of GASTRICID (magnesium hydroxide and calcium carbonate) may modify the frequency and consistency of stools and may cause bloating.

Reporting of side effects

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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.

5. HOW TO STORE GASTRICID

Keep out of the reach and sight of children.

Do not use GASTRICID tablets after the expiry date stated on the outer pack.

Store at a temperature not exceeding 30 °C.

Medicines must not be disposed of down the drain or with the domestic waste. Ask your pharmacist what you should do with unused medicines. These measures are to protect the environment.

6. CONTENT OF THE PACK AND OTHER INFORMATION

What does GASTRICID contain?

The active substances are famotidine (10 mg), magnesium hydroxide (165 mg) and calcium carbonate (800 mg)

The other ingredients are: lactose monohydrate, cellulose acetate, maize starch, magnesium stearate, sodium benzoate (E211), gum arabic, sucralose, hydroxypropylcellulose, hypromellose, crospovidone, spearmint and peppermint flavours.

What GASTRICID looks like and contents of the pack?

This medicine is presented in the form of white round chewable tablet, with a mint flavour, packaged in aluminium strip of 4 tablets.

GASTRICID® is a registered trademark of Exphar s.a. Zoning Industriel de Nivelles Sud, zone 2 - Av. Thomas Edison 105 - 1402 Thines (Belgium)

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