Name of the medicinal product GERDICID 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.

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- 1. WHAT GERDICID IS AND WHAT IT IS USED FOR
- 2. BEFORE YOU TAKE GERDICID
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1. WHAT GERDICID IS AND WHAT IT IS USED FOR

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

GERDICID 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.

<u>Pharmacotherapeutic group</u>: H₂ antagonist/antacid, ATC code: A02BA53 Famotidine, combination

2. BEFORE YOU TAKE GERDICID

Do not take GERDICID in the following cases:

- In case of heartburn and acid regurgitation, chew one tablet
- Prevention: chew one tablet 1 hour prior to the meal
- Do not exceed two tablets per day
- Children under 16 years old

The treatment duration is limited to 2 weeks.

Be careful with GERDICID:

Talk to your doctor or pharmacist: if you have

- symptoms associated with weight loss,
- difficulty swallowing or persistent abdominal discomfort,
- digestive troubles occuring for the first time or if these symptoms have recently changed,
- known hypercalcaemia, as this product contains calcium,
- known hypophosphateamia, as this product may worsen this condition,
- known hypercalciuria, or history of renal calculi or nephrocalcinosis.
- in case of renal failure, this product should be taken under medical supervision and monitoring of serum mangesium and calcium should be undertaken.

- in case of hepatic or renal impairment, this medicine should only be taken under medical supervision and monitoring of serum magnesium and calcium should be undertaken.

If you take GERDICID 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.

If you have an intolerance to some sugars, contact your doctor before taking GERDICID because it contains lactose.

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

Taking other medicines

If you are taking or have recently taken another drug, including a drug obtained without prescription, ask your doctor or pharmacist.

GERDICID contains famotidine and antacids (magnesium hydroxide and calcium carbonate). Do not associate GERDICID with other medicines containing the same ingredients in order to avoid exceeding maximum recommended doses.

GERDICID may interfere with absorption of other medicines. Respect a 2 hours interval between the intake of GERDICID and other drugs. If you are treated by quinolone (antibiotic) respect a 4 hours interval between intakes.

If you have any doubt, do not hesitate to seek advice from your doctor or pharmacist.

Pregnancy and Breastfeeding:

GERDICID is not recommended if you are pregnant, think you are pregnant or planning to become pregnant or breast-feeding.

In general, always ask your doctor or pharmacist before taking a medicine during pregnancy or while breastfeeding.

Driving vehicles and use of machines

Do not drive or operate machines if you experience dizziness.

3. HOW TO TAKE GERDICID

This medicine is not recommended for children under 16 years old.

- heartburn and acid indigestion: chew one tablet. Then preferably swallow with a glass of water.
- prevention: chew one tablet 1 hour before the meal.
- do not take more than 2 tablets in 24 hours and do not exceed 2 weeks of treatment.

If you have taken more GERDICID tablets than you should:

Contact immediately your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, GERDICID chewable tablets may cause side effects, although not everybody gets them:

Frequent: headache

Less frequent: nausea, diarrhoea, nervousness, vertigo, wind, indigestion, burping, dry mouth, thirst, paraesthesia, bloating, abdominal pain and changes in taste.

Very rare:

- skin reactions such as itching, pruritus, rash, urticaria or severe skin bullous reaction.

- allergic reactions including malaise, lips swelling and asthma. In case of swollen face, tongue and/or pharynx oedema, difficulties to swallow or rash with difficulties to breathe, stop using the medicine and talk to your doctor.
- liver disorders, bile secretion discontinuation, liver enzyme abnormalities.
- nervous disorders such as hallucination, confusion, insomnia, seizure, somnolence, agitation and depression.
- blood disorders such as decreased platelets or white blood cells levels, bone marrow alteration and severe anaemia. A decreased white blood cells level may decrease your resistance to infections. Therefore if you notice an infection together with symptoms such as fever and a severe alteration of your general condition, or fever together with symptoms of local infection such as sore throats, pharyngitis or urinary disorders, consult immediately your doctor. Blood analysis will be performed to assess a possible decrease in white blood cells level.
- cramps.
- impotency, decreased libido and breast tenderness.
- alopecia

Magnesium hydroxide and calcium carbonate may modify the frequency and consistence of stools and may cause bloating.

If you notice any side effects not mentioned in this package leaflet, or if some side effects become serious, please tell your doctor or pharmacist.

5. HOW TO STORE GERDICID

Keep out of the reach and sight of children.

Do not use GERDICID 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. FURTHER INFORMATION

What does GERDICID 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 GERDICID 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.

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