

**PATIENT PACKAGE INSERT
IN ACCORDANCE WITH THE
PHARMACISTS' REGULATIONS
(PREPARATIONS) – 1986**

The medicine is dispensed without a doctor's prescription

Gastro 10 Gastro 20 Tablets

The active ingredient and its quantity:
Each **Gastro 10** film-coated tablet contains:
Famotidine 10 mg
Each **Gastro 20** film-coated tablet contains:
Famotidine 20 mg

For the list of inactive and allergenic ingredients in the preparation – see section 6 "Further information".

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

Take the preparation in accordance with the instructions in the Dosage section in this leaflet.

Consult the pharmacist if you need further information. Refer to the doctor if the symptoms worsen or are not improving after 14 days.

The medicine is not intended for use in children below 12 years of age. Below this age, refer to the doctor. The safety of using this medicine in children has not yet been established.

1. WHAT IS THE MEDICINE INTENDED FOR?

- The medicine is used for the prevention and treatment of heartburn and hyperacidity in the upper gastrointestinal tract.

Therapeutic group:

- Inhibitors of gastric acid secretion of the histamine 2 antagonist group.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- you are sensitive (allergic) to the active ingredient famotidine or to any of the additional ingredients contained in the medicine (see section 6 "Further information").
- you experienced an allergic reaction to other medicines containing inhibitors of gastric acid secretion (e.g., ranitidine).
- you are taking additional inhibitors of acid secretion.

Special warnings regarding use of the medicine

Before treatment with Gastro, tell the doctor if:

- you are pregnant or breastfeeding.
- you have difficulty or pain swallowing, severe vomiting, black stools, choking sensation or chest pain, prolonged abdominal pain/discomfort.
- you have a kidney disease; you may need a dosage adjustment.
- you have additional severe diseases.
- you are over the age of 40 and you experience new symptoms or changes in hyperacidity or heartburn symptoms.
- you are taking prescription or non-prescription medicines, e.g., non-steroidal anti-inflammatory drugs (NSAIDs). These medicines, may be causing your symptoms.
- you suffered in the past from gastric ulcer complications.
- you are experiencing unintended weight loss in association with symptoms of hyperacidity or heartburn.
- you have heartburn with light headedness, sweating and dizziness.
- you have chest or shoulder pain with shortness of breath, sweating, pain spreading to arms or neck, or light headedness.

Additional warnings relating to treatment of heartburn

Heartburn and hyperacidity are common events; however, heartburn can be a sign of a serious medical condition, which requires medical intervention.

Stop taking this medicine and additional non-prescription medicines you are taking for hyperacidity and tell the doctor or pharmacist if:

- you are suffering from heartburn symptoms for over 3 months and still have not referred to a doctor.
- the heartburn symptoms persist, worsen or recur after using heartburn medicines for 14 consecutive days.

- you often need to use heartburn medicines for 14 consecutive days (for example, every 6 weeks or more frequently).
- you continue to suffer from heartburn after using this or any other non-prescription medicine to treat heartburn.

Smoking

To avoid symptoms of hyperacidity, cut back on or completely stop using cigarettes.

Children and adolescents

There is no information regarding the safety and effectiveness of use of this preparation in children. The medicine is not intended for use in children under 12 years of age.

Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines or nutritional supplements, tell the doctor or pharmacist. Especially if you are taking:

- itraconazole (for treatment of fungal infections) – taking **Gastro** close to itraconazole can reduce the effectiveness of the antifungal treatment.
- calcium carbonate (antacids) – the effectiveness of the treatment with calcium carbonate is reduced when taken close to **Gastro** (histamine 2 antagonists).

Use of the medicine and food

- It is advisable to avoid foods and beverages that can cause symptoms. Avoid or limit foods and beverages such as: caffeine-containing beverages (coffee, tea, cocoa and cola), chocolate, fried foods, spiced foods or alcohol. Do not lie down immediately after a meal.
- Avoid eating at bedtime.

Additional recommendations

- If you are overweight, weight loss is recommended.
- Raise the head of the bed.
- Wear clothing that is loose-fitting around the stomach.

Use of the medicine and alcohol consumption

Do not drink wines and alcoholic beverages during the course of treatment with the medicine.

Pregnancy, breastfeeding and fertility

Consult the doctor before using the medicine. Consult the doctor before starting treatment if you are pregnant or planning to become pregnant.

Do not use this medicine if you are breastfeeding. Famotidine passes into breast milk.

Driving and operating machinery

Use of this medicine may cause dizziness, and therefore requires caution when driving a vehicle or operating dangerous machinery.

3. HOW SHOULD YOU USE THE MEDICINE?

Check with the doctor or pharmacist if you are uncertain regarding the dosage and treatment regimen of the preparation.

The usual dosage is generally:

Adults and children above 12 years of age:

- **For treatment of heartburn:** One tablet of **Gastro 20** or 2 tablets of **Gastro 10** per day.
- **For prevention of heartburn:** One tablet of **Gastro 20** or 2 tablets of **Gastro 10** per day, with water, one hour before eating food or drinking beverages that may cause heartburn.

Do not exceed the recommended dose.

Duration of treatment

Refer to the doctor if the symptoms worsen or are not improving after 14 days, or if new symptoms develop.

Do not take **Gastro** for more than two consecutive weeks without instruction from the doctor.

Mode of administration

- It is advisable to take the medicine at bedtime.

Halving/Crushing/Chewing:

Do not halve the tablet. There is no information regarding crushing or chewing the tablet.

If you accidentally took a higher dosage, you may suffer from the following symptoms: rapid pulse, sleepy sensation, headache, dizziness, restlessness. There may also be gastrointestinal side effects: stomachaches, nausea, vomiting and diarrhea.

If you took an overdose or if a child has accidentally swallowed the medicine, refer immediately to the doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

If you forgot to take this medicine at the required time, take a dose as soon as you remember. Do not take more than two tablets per day.

Do not take medicines in the dark! Check the label and dose each time you take medicine. Wear glasses if you need them. If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of **Gastro** may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Refer to the doctor immediately if:

- you suffer from allergic reactions such as skin rash, urticaria, swelling, itching and difficulty breathing.
- you suffer from a stomachache, diarrhea, dry mouth, nausea and vomiting.
- you suffer from severe dizziness and sleepiness.

Uncommon side effects, effects that occur in 1-10 in 1,000 users:

Headache, dizziness, weakness and tiredness, stomach discomfort and pain, diarrhea, nausea, vomiting, rash.

Rare side effects, effects that occur in 1-10 in 10,000 users:

Sleepiness, dry mouth, itching.

Side effects of unknown frequency (effects whose frequency has not yet been determined):

Upper stomach pain, urticaria, hypersensitivity, anaphylactic shock, angioedema, itching, changes in results of laboratory tests, liver and kidney function and blood count. These changes are generally insignificant.

Cholestatic jaundice, exhaustion, tiredness, sleepiness, stomach discomfort and pain, upper stomach pain, diarrhea, dry mouth, nausea, vomiting, itching, rash, hypersensitivity, weakness, anaphylaxis, edema, TEN (toxic epidermal necrolysis).

Additional effects that have been reported and for which no causal relationship to famotidine treatment has been proven:

Agitation, confusion, hallucinations, grand mal seizures, rare cases of impotence, reduced blood cell count (thrombocytopenia, pancytopenia, leukopenia and agranulocytosis), gynecomastia.

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il), that directs you to the online form for reporting side effects, or by clicking the link:

<https://sideeffects.health.gov.il>

Additionally, you can report to "Unipharm Ltd."

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine must be kept in a safe place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- **Storage conditions:** Store below 25°C, and in a place protected from light.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:

Pregelatinized Starch, Microcrystalline Cellulose, Talc, Magnesium Stearate, Iron Oxide Red, Opadry Brown OY-9375.

What the medicine looks like and the contents of the package:

Gastro is packed in trays (blisters) inserted into a carton pack.

Gastro 10 is available in package sizes of 2, 4, 6, 8, 10, 20 or 30 tablets.

Gastro 20 is available in package sizes of 20, 30, 50, 100 or 1,000 tablets.

Not all package sizes may be marketed.

Gastro 10 tablets are film-coated, hexagonal, orange tablets with convex edges.

Gastro 20 tablets are film-coated, hexagonal, brown tablets with convex edges.

Registration holder and address: Unipharm Ltd., P.O. Box 21429, Tel Aviv, 6121301.

Manufacturer and address: Unipharm Ltd., "Mevo Carmel" Industrial Park.

Drug Registration Number in the National Drug Registry of the Ministry of Health:

Gastro 10: 107 36 28578 01

Gastro 20: 043 40 26198 02

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