PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

Famotidine Teva 40 mg

Tablets

The active ingredient and its quantity:

Each tablet contains:

Famotidine 40 mg

For information regarding inactive ingredients and allergens, see section 2 - "Important information about some ingredients of the medicine" and section 6 - "Additional information".

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have additional questions, refer to the doctor or the pharmacist.

This medicine has been prescribed for treatment of your illness. Do not pass this medicine on to others. It may harm them even if it seems to you that their medical condition is similar.

This medicine is not intended for use in children under 12 years of age.

You should use the medicine properly. Consult the pharmacist if you need more information.

1. What is the medicine intended for?

The medicine is intended for treatment of conditions in which reduced secretion of gastric juices is required, including treatment of a gastric or duodenal ulcer, esophageal inflammation caused by Gastroesophageal Reflux Disease and Zollinger-Ellison syndrome.

Therapeutic class:

Inhibitors of gastric acid secretion of the histamine 2 antagonists group.

2. Before using the medicine:

Do not use this medicine if:

- You are sensitive to the active ingredient famotidine or to any of the other ingredients the medicine contains or to other medicines of this group (cimetidine, ranitidine or nizatidine).
- You are breastfeeding.

Special warnings regarding the use of the medicine

Before treatment with Famotidine Teva, tell the doctor if:

- You are pregnant or planning to become pregnant.
- You have or have had in the past impaired liver function.
- You have or have had in the past a kidney disease or urinary system impairment.
- You are sensitive to any food or medicine or to ingredients such as preservatives and food coloring.

Smoking

If you smoke, tell your doctor before starting treatment with this medicine. The doctor may advise you to stop smoking or at least to limit smoking.

Children and adolescents

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

Drug interactions

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

- Ketoconazole or itraconazole (for treatment of fungal infections). You should take Famotidine Teva at least two hours after taking ketoconazole or itraconazole.
- Aspirin and other analgesic medicines.
- Atazanavir (for treatment of HIV).
- Sucralfate (for treatment of ulcers).
- Antacids (for treatment of heartburn and indigestion).
- Probenecid (for treatment of gout).

Use of the medicine and food

To prevent irritation of the digestive system, it is advisable to avoid drinking caffeine-containing beverages (coffee, tea, cocoa and cola) or sparkling beverages, and eating food that causes you pain or discomfort (e.g., citrus fruits). Eat smaller and more frequent meals. It is recommended that you eat slowly and chew your food well.

Use of the medicine and alcohol consumption

Do not drink wine or alcoholic beverages during treatment with this medicine.

Pregnancy and breastfeeding

Consult the doctor before using medicines.

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 caution should be exercised when driving a car and operating dangerous machinery.

Important information about some of the ingredients of the medicine

Famotidine Teva 40 mg contains lactose. If you were told by a doctor in the past that you have an intolerance to certain sugars, talk to the doctor before taking this medicine.

3. How should you use the medicine?

Always use the preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the preparation.

The dosage and treatment regimen will be determined only by the doctor. The generally accepted dosage is:

Adults and children over the age of 12 years:

<u>For conditions that require reduced secretion of gastric juices, including treatment of a gastric or duodenal ulcer:</u>

One Famotidine Teva 40 mg tablet in the evening (usually for 4-8 weeks but you may need a longer treatment).

<u>Esophageal inflammation caused by gastroesophageal reflux disease:</u> Half a tablet of Famotidine Teva 40 mg twice daily (morning and evening).

<u>Zollinger-Ellison syndrome:</u> The dosage depends upon the amount of acid the stomach produces. The treating doctor will determine the dosage.

If you have impaired kidney function, the doctor may reduce the dosage.

Do not exceed the recommended dose.

How to use the medicine:

- Do not chew! Swallow the tablet whole with some water.
- It is advisable to take the medicine at bedtime. If you are taking two tablets daily, take one tablet in the morning and one tablet at bedtime.
- You may halve the Famotidine Teva 40 mg tablet at the score line.

If you took an overdose or a child accidentally swallowed this medicine, go to the doctor or the emergency room of the hospital immediately and take the package of the medicine with you.

If you forgot to take this medicine at the required time, take your dose as soon as you remember, but under no circumstances should you take two doses at the same time. Follow the treatment as recommended by the doctor.

If you stop treatment with the medicine

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor.

Do not take medicines in the dark! Check the label and the dose <u>every time</u> you take the medicine. Wear glasses if you need them.

If you have any other questions regarding use of the medicine, consult the doctor or the pharmacist.

4. Side effects:

As with any medicine, using Famotidine Teva may cause side effects in some users. Do not be alarmed when reading the list of side effects, you may not experience any of them.

Stop using the medicine and refer to the doctor immediately if:

- You suffer from any severe skin reaction (such as skin rash, itch, redness, skin ulcers, a burnt appearance)
- You have swelling of the hands, face, lips, tongue or throat (which may cause breathing or swallowing difficulties)
- You have fever, sore throat
- You have tightness in your chest, irregular or reduced heartrate
- You experience unusual weakness or tiredness
- You have an unusual bleeding
- You have liver problems that cause nausea, vomiting, loss of appetite, general malaise, fever, itch, yellowing of the skin and/or the eyes (jaundice) and dark-colored urine
- You have pneumonia
- You suffer from convulsions (very rare), especially in patients with kidney problems

These effects are rare and more serious, and may require urgent medical supervision or hospitalization.

Refer to the doctor immediately if:

- You have blurry vision
- You experience nausea, vomiting, abdominal pain and bloating, dryness of the mouth and skin, loss of appetite
- You suffer from fatigue, drowsiness, sleepiness
- You have muscle and joint pain, muscle cramps
- You experience hallucinations, confusion, irritability, depression, anxiety, inability to fall asleep
- You have tingling in your fingers or toes
- You suffer from decreased sexual function or desire
- You have taste disturbances
- You have buzzing in your ears
- You sweat excessively
- You have unusual hair loss or thinning

Refer to the doctor if:

- You have headaches
- You experience dizziness
- You have constipation, diarrhea

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

Reporting side effects

Side effects may be reported to the Ministry of Health by clicking on the link "Report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link: https://sideeffects.gov.il

5. How to store the medicine?

- **Avoid poisoning!** This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
- Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.
- **Store in a dry place, below 25°C.**
- Do not discard medicines via wastewater or the trash. Ask your pharmacist how to dispose of medicines no longer in use. These measures will help to protect the environment.

6. Additional information

In addition to the active ingredient the medicine also contains:

Microcrystalline cellulose, pregelatinized starch, starch, hydroxypropyl cellulose, magnesium stearate, colloidal silicon dioxide, lactose monohydrate, hydroxypropyl methylcellulose, titanium dioxide, polyethylene glycol, iron oxide yellow, iron oxide red.

Each tablet contains 1.44 mg lactose monohydrate.

What does the medicine look like and what are the contents of the package:

A round, biconvex, light brown to orange coated tablet, scored on one side of the tablet and plain on the other.

Supplied in packs of 20 or 30 tablets in a blister tray. Not all package sizes may be marketed.

Manufacturer, marketing authorization holder and the address:

Teva Israel Ltd.,

124 Dvora HaNevi'a St., Tel Aviv 6944020

Registration number of the medicine in the national drug registry of the Ministry of Health: 111.67.29372

The leaflet was revised in March 2022 in accordance with the Ministry of Health guidelines.

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