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 of the 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.

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 (allergic) to the active ingredient, famotidine, or to any of the other ingredients this medicine contains (see section 6 – "Additional information") or to other histamine H2 receptor antagonists.

Special warnings regarding the use of the medicine

Before treatment with Famotidine Teva, tell the doctor if:

- You suffer from kidney impairment.

Children and adolescents

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

Tests and follow-up

The use of Famotidine Teva 40 mg can mask symptoms of other diseases. Before starting to use the medicine, the doctor may perform tests in order to diagnose your medical condition and rule out other diseases.

If you are taking the medicine at a high dosage and for a long period of time, you may be referred by your doctor for blood and liver function tests.

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). Ketoconazole can be taken at least two hours before taking Famotidine Teva.
- Atazanavir (for treatment of HIV).
- Sucralfate (for treatment of stomach ulcers). Sucralfate should be taken at least two hours after taking Famotidine Teva.
- Antacids (for treatment of heartburn and indigestion). Famotidine Teva can be taken one or two hours before taking antacids.
- Probenecid (for treatment of gout).
- Calcium carbonate, when used as a medicine for high phosphate levels in the blood (hyperphosphatemia) in dialysis patients.

Use of the medicine and food

Famotidine Teva 40 mg can be taken before or after a meal.

Pregnancy and breastfeeding

Consult the doctor before starting treatment if you are pregnant, think you are pregnant or are planning to become pregnant. If you are pregnant while taking Famotidine Teva 40 mg, you should tell your doctor immediately.

Famotidine passes into breast milk. Consult the doctor before taking this medicine if you are breastfeeding or planning to breastfeed.

Driving and operating machinery

Do not drive or operate dangerous machinery if you feel dizzy or have a headache while taking Famotidine Teva 40 mg.

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:

For conditions that require reduced secretion of gastric juices, including treatment of a gastric or duodenal ulcer: one Famotidine Teva 40 mg tablet in the evening. (Usually for 4-8 weeks but you may need a longer treatment).

Esophageal inflammation caused by gastroesophageal reflux disease: half a tablet of Famotidine Teva 40 mg twice daily (morning and evening).

Zollinger-Ellison syndrome: 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! The tablet should be swallowed with some water.
- It is advisable to take the medicine with meals.
- 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. There is no information regarding crushing or chewing of the tablet.

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

If you forgot to take this medicine at the appointed time, take a dose as soon as you remember, unless it is almost time for the next dose. Do not take a double dose, take the next dose at the usual time and consult the doctor.

Follow the treatment as recommended by the doctor.

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 every time you take a 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 a doctor or to the nearest emergency room if:

Very rare side effects, effects that occur in less than one out of 10,000 users:

- You suffer from a severe allergic reaction that includes skin rash, itch or hives, shortness of breath, wheezing or breathing difficulties, swelling of the hands, legs, face, mouth, throat or eyes
- Yellowing of the skin and/or the white of the eyes, dark urine, pale stools, continuous lack of appetite or abdominal pain, which can be signs of serious liver problems
- A very severe rash with blisters, with bleeding in the lips, eyes, mouth, nose and genitals or an acute skin reaction that begins with red painful areas, followed by large blisters, and eventually peeling of the upper skin layer. You may have Stevens-Johnson syndrome or a syndrome called toxic epidermal necrolysis (TEN), which may be life-threatening
- Burning sensation in the chest, shortness of breath or persistent cough, these may be signs of severe pneumonia. In addition, feeling of tiredness, cyanosis of the lips or fingers or weight loss
- Seizures or fits which may be accompanied by loss of consciousness or screaming or jerky movements, an early warning sensation (aura) before, and may be followed by confusion, tiredness or severe headache. If you have a kidney problem you are at a higher risk of seizures
- Changes in the electrical activity of the heart seen on EEG. You may feel dizzy. Patients receiving the medicine by injection have experienced changes in heart rate or irregular heartbeat

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

Very rare side effects, effects that occur in less than one out of 10,000 users:

- Increase in the number of infections, the following symptoms may occur: fever, severe chills, sore throat or mouth ulcers (may be a sign of a decreased amount of white blood cells)
- Low number of blood cells in a blood test, there may be a feeling of tiredness, shortness of breath, a sensation of cold in the hands and feet and skin pallor (low number of red blood cells), abnormal bruising or bleeding more easily than usual and difficulty in healing after a cut (low platelet number)
- Depression, confusion, disorientation, anxiety or irritability, hallucinations (seeing, hearing and sensing things that are not real)

Additional side effects

Common side effects, effects that occur in 1-10 out of 100 users:

- Headaches
- Dizziness
- Constipation or diarrhea

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

- Dry mouth
- Unusual feeling of tiredness
- Nausea and vomiting, loss of appetite, altered sense of taste, flatulence, swelling
- Itching of the skin or rash

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

- Increase in the number of liver enzymes in the blood, seen in blood tests
- Breast growth in men (it is not known for certain whether this side effect is caused by the use of famotidine)

Very rare side effects, effects that occur in less than one out of 10,000 users:

- Difficulty reaching a continuous erection or decreased libido
- Tingling or numbness in the fingers or toes
- Insomnia, drowsiness
- Chest pain
- Change in liver enzyme levels in the blood, seen in blood tests
- Hair loss
- Joint pain or muscle cramps

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.health.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 destroy 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, convex, 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, license 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 December 2023 in accordance with the Ministry of Health guidelines.

Famotidine40 Tab PL MW1223

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