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

This 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 a list of the inactive ingredients, please see Section 6.

Read this leaflet carefully in its entirety before using this medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.
This medicine has been prescribed for the treatment of your ailment. Do not pass this medicine on to others. It may harm them even if it seems to you that their medical condition is similar.
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. You must use the medicine correctly. Consult the pharmacist if you need further 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, gastroesophageal reflux disease and Zollinger-Ellison syndrome.

Therapeutic group:
- Inhibitors of gastric acid secretion of the histamine 2 antagonists group.

2. BEFORE USING THE MEDICINE:

☒ Do not use this preparation if:
- you are breastfeeding.
- you are sensitive to famotidine or to any of the other ingredients of the medicine or to other medicines from this group (cimetidine, ranitidine or nizatidine).

❗ Before treatment with Famotidine Teva®, tell the doctor if:
- you are suffering or have suffered in the past from impaired liver function.
- you are suffering or have suffered in the past from a kidney disease or from an impairment of the urinary tract.
- you are sensitive to any food, medicine or to ingredients such as preservatives and food coloring.

❗ If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell your doctor or pharmacist. It is especially important to inform the doctor or pharmacist if you are taking:
- ketoconazole or itraconazole (for treatment of fungal infections). Famotidine Teva can be taken at least two hours after taking ketoconazole or itraconazole.
- aspirin and other pain relievers.

❗ 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 consumption of alcohol:
Do not drink wine or alcoholic beverages during the course of treatment with the 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 the breast milk.

❗ Driving and using machines:
Use of this medicine may cause dizziness and therefore, caution should be exercised when driving a car or operating dangerous machinery.

❗ 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.

❗ Important information about some of the ingredients of the medicine:
Famotidine Teva 40 mg contains lactose (1.44 mg lactose in each tablet) and may cause allergy in people sensitive to lactose. If you are intolerant to certain sugars, consult the doctor before taking this medicine.

3. HOW SHOULD YOU USE THE MEDICINE?

- Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure.

The dosage and treatment regimen will be determined by the doctor only.
The usual dosage is generally:
Adults and children above 12 years of age:
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. (Generally for 4-8 weeks but you may need a longer treatment).
Gastroesophageal reflux disease: Half a tablet of Famotidine Teva 40 mg twice daily (in the morning and evening).
Zollinger-Ellison syndrome: The dosage depends upon the amount of acid the stomach produces. The attending doctor will determine the dosage. If you have impaired kidney function, the doctor may reduce the dosage.
Do not exceed the recommended dosage.

Instructions for use of the medicine:
- Do not chew! Swallow the tablet whole with a small amount of water.
- It is advisable to take the medicine before bedtime. If you are taking two tablets daily take one tablet in the morning and one tablet before bedtime. You may divide the Famotidine Teva 40 mg tablet on the score line.

If you have taken 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 forget to take this medicine at the specified time, take a dose as soon as you remember, but never take two doses together.
Adhere to the treatment 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 each time you take a 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 Famotidine Teva 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.

Stop using the medicine and refer to the doctor immediately if:
- you suffer from any severe skin reaction (such as skin rash, itching, redness, skin ulcers, a burnt appearance).
- you have swelling of the hands, face, lips, tongue or throat (that may cause breathing or swallowing difficulties).
- you have fever, a sore throat.
- you have tightness in your chest, irregular or reduced heartbeat rate.
- you experience unusual weakness or tiredness.
- you have unusual bleeding.
- you have liver problems that cause nausea, vomiting, loss of appetite, a generally unwell feeling, fever, itching, yellowing of the skin and/or 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 blurred 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, agitation, 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 the 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 any of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult the doctor.

5. HOW SHOULD THE MEDICINE BE STORED?

- **Avoid poisoning!** This medicine and all other medicines must be stored 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) appearing on the package. The expiry date refers to the last day of that month.
- Store in a dry place at a temperature below 25ºC.
- Do not discard medicines in the water waste or trash bin. Ask the pharmacist how to discard medicines that are no longer in use. These measures will help protect the environment.

6. FURTHER 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 (1.44 mg), hydroxypropyl methylcellulose, titanium dioxide, polyethylene glycol, iron oxide yellow, iron oxide red.

What does the medicine look like and what are the contents of the package:
A round, convex tablet, brownish-yellow in color, with a score line on one side of the tablet only.
Supplied in packs of 20 or 30 tablets in a blister tray.

Manufacturer, license holder and address:
Teva Pharmaceutical Industries Ltd., POB 3190, Petach-Tikva.

Drug Registration No. in the National Drug Registry of the Ministry of Health: 111.67.29372.11

This leaflet was checked and approved by the Ministry of Health in December 2012.

TEVA