PATIENT PACKAGE INSERT
IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986
This medicine is dispensed without a doctor's prescription

FAMOTIDINE TEVA 20 mg

Tablets

The active ingredient and its quantity:
Each tablet contains:
Famotidine 20 mg

For information about inactive and allergenic ingredients in the medicine, see section 2 "Important information about some of the ingredients of the medicine" and section 6 "Further Information".

Read the 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.

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 from the histamine 2 antagonist group.

2. BEFORE USING THE MEDICINE:

Do not use the medicine if:
- you are sensitive (allergic) to 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 Famotidine Teva, tell the doctor if:
- you are pregnant or breastfeeding.
- you have difficulty or pain swallowing, severe vomiting, black stools, choking sensation, 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 symptoms of hyperacidity or heartburn.
- 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 are taking a proton pump inhibitor (PPI) medicine.
- you frequently (more than 3 times a week) suffer from heartburn and/or from severe heartburn.
- you have heartburn accompanied by dizziness or sweating.
- you have chest or shoulder pain accompanied by shortness of breath, sweating, pain spreading to arms or neck, or dizziness.

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 refer to 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 medicine in children. The medicine is not intended for use in children under 12 years of age.

Drug interactions
If you are taking, or if you have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. In particular, if you are taking:
- itraconazole (for treatment of fungal infections). Taking Famotidine 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 Famotidine (histamine 2 antagonist).

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, spicy 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 wine or alcoholic beverages during the course of treatment with the medicine.

Pregnancy and breastfeeding
Consult the doctor before using the medicine.
Consult the doctor before starting treatment if you are pregnant or are 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 vehicle or operating dangerous machinery.

Important information about some of the ingredients of the medicine
Famotidine Teva 20 mg contains lactose and may cause allergy in people sensitive to lactose. If you have a sensitivity to certain sugars, consult a doctor before taking this medicine.

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 Famotidine Teva 20 mg tablet per day.
For prevention of heartburn: one Famotidine Teva 20 mg tablet 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 Famotidine Teva 20 mg for more than two consecutive weeks without instruction from the doctor.

Instructions for use of the medicine:
- It is advisable to take the medicine before bedtime.
- Swallow the tablet whole with a small amount of water.
- Do not halve the tablet, as the tablet has no score line.
- 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 forget to take this medicine at the required time, take a dose as soon as you remember, but never take more than two tablets per day.

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 20 mg 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 have a stomachache, diarrhea, dry mouth, nausea, constipation and vomiting.
- you suffer from severe dizziness and sleepiness.

Common side effects (effects that occur in 1-10 in 100 users):
- headache
- diarrhea, vomiting, constipation, nausea
- lung inflammation, laryngitis, flu-like illness
- back pain
- itching

Uncommon side effects (effects that occur in 1-10 in 1,000 users):
- dizziness
- weakness and tiredness, stomach discomfort and pain, chest pain, muscle pains
- anxiety, dizziness, sinusitis, lump in the breast

Rare side effects (effects that occur in 1-10 in 10,000 users):
- sleepiness
- dry mouth
- itching
- toxic epidermal necrolysis-type skin reaction
- heart rate disturbances

Side effects of unknown frequency (effects whose frequency has not yet been determined):
- urticaria-type rash, hypersensitivity, anaphylactic reaction (a severe allergic reaction), angioedema
- changes in results of laboratory tests, in liver and kidney function tests and in blood count. These changes are generally insignificant
- cholestatic jaundice, malaise

Additional effects that have been reported and for which no causal relationship to famotidine treatment has been proven:
Agitation, confusion, hallucinations, depression, disorientation, mental disturbance, insomnia, hair loss, photosensitivity, Stevens-Johnson-type skin rash, taste disturbances, prickling/numbness in the hands or legs, grand mal seizures, fainting, rare cases of impotence, reduced blood cell count (anemia, neutropenia, thrombocytopenia, pancytopenia, leukopenia and agranulocytosis), reversible breast enlargement in men (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.

Reporting of side effects
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 entering the link:
https://sideeffects.health.gov.il

5. HOW SHOULD THE MEDICINE BE STORED?

- **Avoid poisoning!** This medicine and any other medicine must be stored in a safe place out of the reach and sight of children and/or infants in order 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) that appears on the package. The expiry date refers to the last day of that month.
- **Store in a dry place below 25°C.**

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 (0.72 mg), hydroxypropyl methylcellulose (hypromellose), 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, biconvex, film-coated tablet, brownish-orange in color.
There are packages of 20 or 30 tablets packed in trays (blister). Not all package sizes may be marketed.

Name of Manufacturer and License Holder and 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: 111.66.29371

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