

## Package leaflet: Information for the user

### FamoNor 20 mg film-coated tablets

Famotidine

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

### **What is in this leaflet:**

1. What FamoNor is and what it is used for
2. What you need to know before you take FamoNor
3. How to take FamoNor
4. Possible side effects
5. How to store FamoNor
6. Contents of the pack and other information

### **1. What FamoNor is and what it is used for**

FamoNor belongs to the group of medicines called histamine H<sub>2</sub>-receptor antagonists or H<sub>2</sub>-blockers. Famotidine works by reducing the amount of acid that your stomach produces.

Famotidine is indicated in the treatment of duodenal ulcer, benign gastric ulcer, as well as in the prevention of their relapses. It is also used for other diseases in which the stomach produces too much acid, as the Zollinger-Ellison syndrome, and for the gastroesophageal reflux disease and esophagitis due to gastroesophageal reflux.

FamoNor is indicated in adults.

### **2. What you need to know before you take FamoNor**

#### **Do not take FamoNor**

- If you are allergic (hypersensitive) to famotidine, any of the other H<sub>2</sub>-receptor antagonists or any of the other ingredients of this medicine (listed in section 6).

#### **Warnings and precautions**

- Before starting treatment, your doctor shall rule out the existence of other more serious diseases. The relief of symptoms of gastric ulcer during treatment may delay the diagnosis of other diseases.
- You should not stop treatment abruptly. Treatment suspension shall be gradually and according to your doctor's indications to avoid relapses.

Talk to your doctor or pharmacist before taking FamoNor:

- If you have any moderate or severe kidney disease. Your doctor shall indicate you the lowest administration frequency or the lowest dose you should take.
- If you are an elderly person, as you may have kidney problems.

### **Children and adolescents**

Safety and efficacy of this medicine have not been established in children.

### **Use in patients older than 65 years**

Patients older than 65 years only require a dose adjustment in case of moderate or severe kidney failure.

### **Other medicines and FamoNor**

Tell your doctor if you are taking, have recently taken or might take any other medicines.

- Calcium carbonate, when it is used to treat elevated blood phosphorus levels (hyperphosphatemia) in patients on dialysis.

### **Pregnancy and breast-feeding**

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Treatment with famotidine is not recommended during pregnancy. You should inform your doctor if you are pregnant or planning to become pregnant.

Famotidine has been detected in breast milk. Breast-feeding mothers should stop treatment with famotidine or suppress lactation.

### **Driving and using machines**

Although effects in this sense are not expected, if dizziness occurs, you should not drive or use dangerous machinery.

## **3. How to take FamoNor**

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

Treatment of duodenal ulcer: The recommended dose is 2 tablets (40 mg of famotidine) at night. Likewise, it is possible to administer 1 tablet (20 mg of famotidine) every 12 hours. Treatment should be followed for 4 to 8 weeks.

Treatment of benign gastric ulcer: The recommended dose is 2 tablets (40 mg of famotidine) at night. Treatment should be followed for 4 to 8 weeks.

Maintenance treatment of duodenal or gastric ulcer: It is recommended to take 1 tablet (20 mg of famotidine) at night. Your doctor will tell you how long to take your medicine.

Treatment of gastro-oesophageal reflux disease (GERD): the recommended dose is 1 tablet (20 mg of famotidine), twice daily. If your condition does not improve within 4-8 weeks, talk to your doctor.

Treatment of esophagitis due to gastro-oesophageal reflux: the recommended dose is 2 tablet (40 mg of famotidine), twice daily. If your condition does not improve within 4-8 weeks, talk to your doctor.

Zollinger-Ellison syndrome: Treatment will usually start by one dose of 1 tablet (20 mg) every 6 hours. The doctor will adjust the dose subsequently depending on the needs of each patient.

It is very important that you keep taking this medicine for as long as your doctor has prescribed it because pain usually disappears before the ulcer is completely healed.

### **Use in patients with moderate or severe renal insufficiency**

Your doctor will decide whether it is necessary to adjust the dose either reducing it by half or increasing the time between doses.

Elderly patients only require a dose adjustment in case of kidney failure.

### **Method of administration**

Swallow the tablet with water. You can take FamoNor with or without food.

The tablet can be divided into equal halves.

Your doctor will tell you how many tablets to take daily and how long to take them for. Do not stop the treatment earlier. If you feel that the effect of this medicine is too strong or too weak, talk to your doctor or pharmacist.

### **If you take more FamoNor than you should**

In case of overdose or accidental intake, contact your doctor or pharmacist immediately or go to the nearest hospital, indicating the medicine and the amount taken. Take this leaflet or the package with you if possible and show it to the health professionals.

### **If you forget to take FamoNor**

Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

## **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

### **Common (may affect up to 1 in 10 people):**

- Headache
- Dizziness
- Diarrhoea
- Constipation

### **Uncommon (may affect up to 1 in 100 people):**

- Lack of appetite
- Fatigue

- Nausea
- Vomiting
- Abdominal distension or discomfort
- Dry mouth
- Excess of intestinal gas
- Skin rash
- Itching
- Joint pain
- Muscle cramp
- Reversible psychic disorders including depression, anxiety disorders, agitation, confusion, and hallucinations.

**Rare (may affect up to 1 in 1,000 people):**

- Cholestatic jaundice (yellowing of skin and eyes due to problems with the secretion of bile)
- Urticaria (spots on the skin)
- Anaphylaxis (unusual or exaggerated allergic reaction)
- Angioneurotic oedema (severe allergic reaction with wheezing, hives, and swelling of the face, lips, tongue, throat, and even extremities with difficulty swallowing or breathing)

**Very rare (may affect up to 1 in 10,000 people):**

- Loss of hair
- Laboratory findings: Anomalies of liver enzymes
- Toxic epidermal necrolysis (skin peeling)

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please inform your doctor or pharmacist.

**Reporting of side effects:**

If you get any adverse effects talk to your doctor, pharmacist, or nurse. This includes any possible adverse effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

**5. How to store FamoNor**

Keep this medicine out of the sight and reach of children.

No special storage conditions are required.

Do not use this medicine after the expiry date which is stated on the container. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines and packs you no longer use. These measures will help protect the environment.

**6. Contents of the pack and other information**

**What FamoNor contains**

- The active substance is famotidine. Each tablet contains 20 mg of famotidine.
- The other ingredients (excipients) are:
  - Tablet core: pregelatinized maize starch, microcrystalline cellulose, talc, magnesium stearate.

- Tablet coat: hypromellose, titanium dioxide (E-171), macrogol 6000 and yellow iron oxide (E-172).

**What FamoNor looks like and contents of the pack**

FamoNor 20 mg film-coated tablets is supplied in Aluminium/PVC blisters. Each pack contains 28 yellow, round, biconvex, and scored film-coated tablets.

**Marketing authorisation holder and manufacturer**

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