Famodar®

Famotidine

Read all of this leaflet carefully before you start taking this medicine.
- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Famodar® tablets are and what they are used for

Famodar® tablets contain a medicine called famotidine (either 20 mg or 40 mg). This belongs to a group of medicines called 'H2-blockers'. **Famodar®** works by lowering the amount of acid you produce in your stomach.
Famodar® is used for:
– Preventing ulcers in your stomach (gastric ulcer) or the first part of your intestine (duodenal ulcer)
– Healing ulcers and to give you relief from symptoms. **Famodar®** may also be used to lower the chance that your duodenal ulcer will come back
– Treating 'gastro-oesophageal reflux disease' (GORD) caused by stomach acid and food from your stomach going backup into your food pipe (oesophagus), or for preventing the symptoms from coming back
– 'Zollinger-Ellison syndrome' where your stomach produces too much acid.
Talk to your doctor if you have any questions about this.

2. Before you take Famodar® tablets

Do not take Famodar® if:
– you have ever had an allergic reaction to the active ingredient of this medicine or to any of the other ingredients
– you have ever had an allergic reaction to a similar medicine
– you are or think you may be pregnant
– you are planning to become pregnant
– you are breast-feeding
Do not take **Famodar®** if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking **Famodar®**.
Children
Famodar® should not be used in children.

Take special care with Famodar®
Check with your doctor or pharmacist before taking your medicine if you have kidney problems.
Your doctor may check your blood count and liver function, if you have been taking high dose of **Famodar®** for a long time.
It is important that you do not suddenly stop taking **Famodar®** without talking to your doctor if you have had ulcer disease for a long time.

Taking other medicines, herbal or dietary supplements
Please tell your doctor if you are taking or have recently taken any other medicines, including those obtained without a prescription. In particular you should tell your doctor or pharmacist if you are taking any of the following medicines:
- Probenecid, used for gout or arthritis caused by gout
- Itraconazole or ketoconazole, used for fungal infections
- Atazanavir, used for treatment of HIV infection
- Antacids, used for treatment of heartburn or acid indigestion
- Sucralfate, used for treatment of ulcers

Driving and using machines
Some patients have experienced adverse reactions such as dizziness and headache while taking famotidine. Do not drive or operate machinery until you see how **Famodar®** affects you and whether you experience these symptoms.

Important information about some of the ingredients of Famodar®
Famodar® 20 mg and 40 mg tablets contain sunset yellow (E110), in addition to red carmoisine (E122) in **Famodar®** 40 tablets, which may cause allergic reaction.

3. How to take Famodar® tablets

Taking this medicine
You should take this medicine by mouth. The number of tablets you take each day will depend upon your condition and whether you have kidney problems.
– Swallow the tablet with water
– Do not take more or less than your doctor has prescribed
– You should keep taking the tablets for as long as your doctor has asked, even though you may feel better very quickly.
– It is important that you do not stop taking the tablets without talking to your doctor.
The usual doses are:
For an ulcer
- Treatment: One 40 mg tablet at night, for 4 to 8 weeks. This may change depending on how you respond to the treatment.
- Prevention: One 20 mg tablet at night.

For 'gastro-oesophageal reflux disease' (GORD)
- Prevention of mild symptoms: One 20 mg tablet in the morning and one 20mg tablet at night.
- Treatment of mild symptoms: One 20 mg tablet in the morning and one 20mg tablet at night, for 6 to 12 weeks.
- Treatment of more severe symptoms: One 40 mg tablet in the morning and one 40 mg tablet at night, for 6 to 12 weeks.

For 'Zollinger-Ellison Syndrome'
- One 20 mg tablet every six hours.
- Some patients may need higher doses for this condition.

If you take more Famodar® than you should
Please contact your doctor immediately.

If you forget to take Famodar®
Do not take an extra dose. Take the normal amount of **Famodar®** the next time you are due to take a 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, **Famodar®** can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:
Common (affects less than 1 in 10 people)
– Headache, dizziness
– Constipation, diarrhea
Uncommon (affects less than 1 in 100 people)
If you have an allergic reaction, stop taking **Famodar®** and see a doctor straight away. The signs may include:
– Swelling of your face, lips, tongue or throat (with difficulty in breathing or swallowing)
– Hives
– Dry mouth, changes in taste
– Feeling sick, vomiting
– Mild stomach (abdominal) pain or bloating
– Rash
– Loss of appetite
– Feeling tired
– Itching
Very rare (affects less than 1 in 10,000 people)
– Wheezing or difficulty swallowing
– Feeling depressed, anxious, agitated, confused or seeing or hearing things that are notthere (hallucinations) and disorientation. These usually go away after stopping **Famodar®**
– difficulty sleeping
– seizures in people with kidney problems
– tingling feeling or numbness
– less desire to have sex
– severe skin reactions known as Stevens-Johnson Syndrome/or toxic epidermal necrolysis
– slow or irregular heart beat
– pneumonia (sometimes severe), painful joints, muscle cramps
– yellowing of your skin or whites of your eyes, (jaundice)
– abnormal liver blood tests
– lowered blood-cell counts (usually seen in a blood test)
– hair loss
– being unable to have an erection (impotence)
Not known
– Breast enlargement in men (although this may not have been caused by **Famodar®**)

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist. It will help if you make a note of what happened, when it started and how long it lasted.

5. How to store Famodar® tablets

- Keep out of the reach and sight of children.
- Do not take **Famodar®** after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.
- Protect from light. Store in a dry place. Do not store above 30°C.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What Famodar® contains
Famodar® 20 Film coated tablets: Each tablet contains 20 mg famotidine as the active ingredient.
Famodar® 40 Film coated tablets: Each tablet contains 40 mg famotidine as the active ingredient.
Famodar® film coated tablets also contain microcrystalline cellulose, pregelatinized starch, magnesium stearate, talc, hypromellose, titanium dioxide, macrogol, sunset yellow (E110), **Famodar®** 40 tablets also contain red carmoisine (E122) and indigo carmine (E132).

What Famodar® looks like and contents of the pack
Famodar® 20 tablets are yellow orange round normal biconvex film coated tablets, coded (FAM 20) on one side, plain on the other side.
Famodar® 40 tablets are brick-colored round normal biconvex film coated tablet coded (FAM 40) on one side, plain on the other side.
Famodar® tablets are packed in blisters of 10. **Famodar®** 20 mg film coated tablets are available in packs of 20 (two blisters), 30 (three blisters), 400 (40 blisters), 500 (50 blisters). **Famodar®** 40 mg film coated tablets are available in packs of 10 (one blister), 400 (40 blisters), 500 (50 blisters).
Not all pack sizes may be marketed.

Marketing authorization holder and manufacturer
Dar Al Dawa Development & Investment Co. Ltd. (Na'ur-Jordan)
Tel. (+962 6) 57 27 132
Fax. (+962 6) 57 27 776

To report any side effects:
- Jordan
  – Contact marketing authorization holder
- Saudi Arabia
  – National Pharmacovigilance and Drug Safety Centre (NPC)
  – Fax: + 966 112057662
  – Call NPC at + 966 112038222, Exts: 2317-2356-2353-2354-2334-2340
  – Toll free phone: 8002490000
  – E-mail: npc.drug@sfda.gov.sa
  – Website: www.sfda.gov.sa/npc
- United Arab Emirates
  – Pharmacovigilance and Medical Device Section
  – Drug Department
  – UAE MOH
  – Hotline: 80011111
  – Email: pv@moh.gov.ae
  – P.O. Box: 1853 Dubai UAE
- Sudan
  – National Medicines and Poisons Board (NMPB)
  – Fax: + 249 183522263
  – E-mail: info@nmpb.gov.sd
  – Website : www.nmpb.gov.sd
- Other countries
  – Please contact the relevant competent authority.

This is a Medicament

– Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
– Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
– The doctor and the pharmacist are the experts in medicines, their benefits and risks.
– Do not by yourself interrupt the period of treatment prescribed for you.
– Do not repeat the same prescription without consulting your doctor.
– Keep all medicaments out of reach of children.

Council of Arab Health Ministers and Union of Arab Pharmacists

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08/2014

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