FEOSTA® 200

(Ferrous fumarate 200mg)

Patient Information Leaflet

<u>Warning:</u> Accidental overdose of products that contain iron is a leading cause of fatal poisoning in children younger than 6 years old. Keep this product out of the reach of children. In case of accidental ingestion, call a doctor.

Feosta is used for:

Supplementing iron in the diet and preventing or treating low levels of iron in the blood. It also may be used for other conditions as determined by your doctor. Feosta is an essential body mineral. It works by providing iron to the body.

Do NOT use Feosta if:

- you are allergic to any ingredient in Feosta
- Inactive ingredients: Corn starch, Talc, Magnesium stearate, PVP K30.
- you have certain iron metabolism problems (eg, hemosiderosis, hemochromatosis) or high levels of iron in your blood

Contact your doctor or health care provider right away if any of these apply to you.

Before using Feosta:

Some medical conditions may interact with Feosta. Tell your doctor or pharmacist if you have any medical conditions, especially if any of the following apply to you:

- if you are pregnant, planning to become pregnant, or are breast-feeding
- if you are taking any prescription or nonprescription medicine, herbal preparation, or dietary supplement
- if you have allergies to medicines, foods, or other substances
- if you have stomach or bowel problems (eg, colitis, Crohn disease, diverticulitis, ulcers)
- if you have hemolytic anemia, pernicious anemia, or other types of anemia, or if you have a condition that may cause anemia (eg, sickle cell disease, glucose-6-phosphate dehydrogenase [G6PD] deficiency)
- if you have blood problems (eg, porphyria, thalassemia) or you have had multiple blood transfusions Some MEDICINES MAY INTERACT with Feosta. Tell your health care provider if you are taking any other medicines, especially any of the following:
 - Doxycycline, mycophenolate, penicillamine, or thyroid hormones (eg, levothyroxine) because their effectiveness may be decreased by Feosta

This may not be a complete list of all interactions that may occur. Ask your health care provider if Feosta may interact with other medicines that you take. Check with your health care provider before you start, stop, or change the dose of any medicine.

How to use Feosta:

Use Feosta as directed by your doctor. Check the label on the medicine for exact dosing instructions.

- Feosta is absorbed better on an empty stomach but may be taken with food if it upsets your stomach. Some foods (eg, eggs, whole grain breads, cereal, dairy products, coffee, tea) may decrease the amount of iron absorbed by your body. Talk with your doctor about the best way to take Feosta with food if it upsets your stomach.
- If you take an antacid, a bisphosphonate (eg, alendronate), cefdinir, eltrombopag, methyldopa, penicillamine, a quinolone antibiotic (eg, ciprofloxacin), or a tetracycline antibiotic (eg, minocycline), ask your doctor or pharmacist how to take it with Feosta.
- Take Feosta with a full glass of water (8 oz [240 mL]). Do not lie down for 30 minutes after taking Feosta.

• If you miss a dose of Feosta, take it as soon as possible. If it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not take 2 doses at once.

Ask your health care provider any questions you may have about how to use Feosta.

Important safety information:

- Do not take large doses of vitamins (megadoses or megavitamin therapy) while you use Feosta unless otherwise directed by your doctor.
- Do NOT take more than the recommended dose without checking with your doctor.
- Feosta has iron in it. Before you start any new medicine, check the label to see if it has iron in it too. If it does or if you are not sure, check with your doctor or pharmacist.
- Feosta may cause darkened or green stools. This is normal and not a cause for concern.
- Feosta may interfere with certain lab tests, including tests used to check for blood in the stool. Be sure your doctor and lab personnel know you are taking Feosta.
- Lab tests, including hematocrit, hemoglobin levels, and blood iron levels, may be performed while you use Feosta. These tests may be used to monitor your condition or check for side effects. Be sure to keep all doctor and lab appointments.
- Feosta should be used with extreme caution in CHILDREN; safety and effectiveness in children have not been confirmed.
- PREGNANCY and BREAST-FEEDING: If you become pregnant, contact your doctor. You will need to
 discuss the benefits and risks of using Feosta while you are pregnant. Feosta is found in breast milk. If you
 are or will be breast-feeding while you use Feosta, check with your doctor. Discuss any possible risks to
 your baby.

Possible side effects of Feosta:

All medicines may cause side effects, but many people have no, or minor, side effects. Check with your doctor if any of these most COMMON side effects persist or become bothersome: Constipation; dark or green stools; diarrhea; loss of appetite; nausea; stomach cramps, pain, or upset; vomiting.

Seek medical attention right away if any of these SEVERE side effects occur:

Severe allergic reactions (rash; hives; itching; difficulty breathing; tightness in the chest; swelling of the mouth, face, lips, or tongue); black, tarry stools; blood or streaks of blood in the stool; fever; severe or persistent nausea, stomach pain, or vomiting; vomit that looks like blood or coffee grounds.

If OVERDOSE is suspected:

Go to emergency room immediately. Symptoms may include black, tarry stools; blood or streaks of blood in the stool; bluish skin or nails; changes in the amount of urine produced; chest pain; coma; dizziness; dry mouth or eyes; fainting; fast or difficult breathing; fast or irregular heartbeat; flushing; increased thirst or hunger; seizures; severe nausea, vomiting, diarrhea, or stomach pain; severe or unusual tiredness or drowsiness; shortness of breath; sluggishness; unusually pale skin; vomit that looks like blood or coffee grounds.

Proper storage of Feosta:

Store Feosta at room temperature 15 and 30 degrees C. Store away from heat, moisture, and light. Do not store in the bathroom. Keep Feosta out of the reach of children and away from pets.

General information:

- If you have any questions about Feosta, please talk with your doctor, pharmacist, or other health care provider.
- Feosta is to be used only by the patient for whom it is prescribed. Do not share it with other people.
- If your symptoms do not improve or if they become worse, check with your doctor.
- Check with your pharmacist about how to dispose of unused medicine.

Issue Date: 05/2014

Marketing Authorisation Holder and Manufacturer PHARMADEX s.a.l ,Kahale,Lebanon



THIS IS A MEDICATION	إن هذا الدواء
-Medication is a product wich affects	- الدواء يؤثر على صحتك واستهلاكه خلافا
Your health and its consumption contrary	للتعليمات يعرضك للخطر. يتبع بدقة وصفة الطبيب،
To instructions is dangerous for you.	طريقة الاستخدام والتعليمات من الصيدلي الذي صرفها لك.
Follow strictly the doctor's prescription,	, <u> </u>
The method of use and the instructions	
Of the pharmacist who sold the medication.	
	-الطبيب والصيدلي هما الخبيران
-The doctor and the pharmacist are the experts	في الدواء وفوائده ومخاطره.
In medicines, their benefits and risks.	A company to the second
	-لا يقطع مدة العلاج المحددة لك من تلقاء نفسك.
-Do not interrupt by yourself the period of	
Treatment prescribed.	- لا تكرر صرف الدواء دون استشارة الطنيب
Do not man at the come man animation with out	استساره الطبيب.
-Do not repeat the same prescription without	- تحفظ جميع الأدوية بعيدا عن متناول الأطفال
Consulting your doctor.	- تحفظ جميع الأدوية بغيدا على منكون الإصفان
-Keep all medications out of reach of children.	