



# **FIRMAGON<sup>®</sup>** (degarelix for injection)

## **17.2 FDA-approved Patient Labeling**

### **FIRMAGON (FIRM-uh-gahn) (degarelix for injection)**

Read this patient information leaflet before you start taking FIRMAGON and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment.

#### **What is FIRMAGON?**

FIRMAGON is a prescription medicine used in the treatment of advanced prostate cancer.

It is not known if FIRMAGON is safe or effective in children.

#### **Who should not use FIRMAGON?**

FIRMAGON should not be given to:

- people who are allergic to any ingredient in FIRMAGON. See the end of this leaflet for a complete list of ingredients in FIRMAGON.
- women who are pregnant or may become pregnant

Talk to your healthcare provider before getting FIRMAGON if you have any of these conditions.

#### **What should I tell my healthcare provider before receiving FIRMAGON?**

**Before receiving FIRMAGON, tell your healthcare provider about all your medical conditions, including if you:**

- have any heart problems
- have problems with balance of your body salts or electrolytes, such as sodium, potassium, calcium, and magnesium
- have kidney or liver problems
- are breast-feeding or plan to breast-feed. It is not known if FIRMAGON passes into your breast milk. You and your healthcare provider should decide if you will take FIRMAGON or breast-feed. You should not do both without talking with your healthcare provider.

**Tell your healthcare provider about all the medicines you take**, including prescription and nonprescription medicines, vitamins, and herbal supplements. Especially tell your healthcare provider if you are taking or have taken any medicines for your heart.

Know the medicines you take. Keep a list of them and show it to your healthcare provider and pharmacist when you get a new medicine.

## **How should I receive FIRMAGON?**

You will receive an injection of FIRMAGON from your healthcare provider.

- The injection site will always be in the abdominal area but will change within that area with the next doses of FIRMAGON.
- The injected medicine gives you a continuous release of FIRMAGON over one month.
- Two injections are given as a first dose and the following monthly doses are one injection.
- Make sure your injection site is free of any pressure from belts, waistbands or other types of clothing.
- Always set up an appointment for your next injection.
- If you miss a dose of FIRMAGON, or if you think you forgot to get your monthly dose of FIRMAGON, talk to your healthcare provider about how to get your next dose.

## **What are the possible side effects of FIRMAGON?**

The common side effects include:

- hot flashes
- injection site pain, redness, and swelling, especially with the first dose
- weight gain
- increase in some liver enzymes
- tiredness
- hypertension
- back and joint pain
- chills
- urinary tract infection
- decreased sex drive and trouble with erectile function (impotence)

These are not all the possible side effects. For more information, ask your healthcare provider or pharmacist.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

## **General information about the safe and effective use of FIRMAGON.**

Medicines are sometimes prescribed for conditions that are not mentioned in the patient leaflet. Do not use FIRMAGON for a condition for which it was not prescribed. Do not give FIRMAGON to other people, even if they have the same symptoms that you have. It may harm them.

This patient information leaflet summarizes the most important information about FIRMAGON. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about FIRMAGON that is written for health professionals.

For more information, go to [www.FIRMAGON.com](http://www.FIRMAGON.com) or call 1-888-FERRING (1-888-337-7464)

### **What are the ingredients in FIRMAGON?**

Active ingredient: degarelix (as acetate)

Inactive ingredient: mannitol

Manufactured for:  
Ferring Pharmaceuticals Inc., Parsippany, NJ 07054  
By: Rentschler Biotechnologie GmbH, Germany

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