

## FIRMAGON®

### Powder and Solvent for Injection, depot

Degarelix (as acetate)

## Consumer Medicine Information

### What is in this leaflet

This leaflet answers some common questions about Firmagon.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking/being given Firmagon against the benefits they expect it will have for you.

**If you have any concerns about taking this medicine, ask your doctor or pharmacist.**

**Keep this leaflet with the medicine.**

You may need to read it again.

### What Firmagon is used for

Firmagon contains degarelix.

Degarelix is a synthetic hormone that reduces the level of the male hormone, testosterone.

Firmagon is used to treat:

- prostate cancer

Firmagon may slow or stop the growth of cancer.

Firmagon should only be taken by men. It should not be taken by women or children.

**Ask your doctor if you have any questions about why Firmagon has been prescribed for you.**

Your doctor may have prescribed Firmagon for another reason.

Firmagon is not addictive.

This medicine is available only with a doctor's prescription.

### Before you are given Firmagon

#### *When you must not be given it*

**Firmagon will not be given if you have an allergy to:**

- degarelix, the active ingredient in Firmagon or any similar drugs, known as GnRH antagonists (blockers)
- any of the other ingredients of Firmagon listed at the end of this leaflet.

Symptoms of an allergic reaction may include:

- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

**You must not be given Firmagon after the expiry date (EXP) printed on the pack.**

**You must not be given Firmagon if the packaging is torn or shows signs of tampering.**

If it has expired or is damaged, return it to your pharmacist for disposal.

#### *Before you are given it*

**Tell your doctor if you have allergies to:**

- any other medicines
- any other substances, such as foods, preservatives or dyes.

**Tell your doctor if you have or have had any medical conditions, especially the following:**

- heart problems, including angina (non-compensated cardiac insufficiency, angina)

- high blood pressure (hypertension)

If you have not told your doctor about any of the above, tell them before you start taking Firmagon.

#### *Taking other medicines*

**Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.** Some medicines and Firmagon may interfere with each other.

These include:

- medicines regulating heart rhythm, e.g. quinidine, procainamide, amiodarone and sotalol
- medicines obtained without a prescription.

These medicines may be affected by Firmagon, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while taking Firmagon.

### How Firmagon is given

The powder and solvent are mixed and injected by your doctor or a nurse in your stomach region.

The injected liquid forms a depot from which a continuous release of degarelix takes place over a period of one month.

#### *How much you will be given*

Two injections of 120 mg are given as a first dose. For all subsequent doses one injection of 80 mg is given every month.

Instructions for proper use of the drug intended for your doctor or nurse are included in the package insert.

#### *How it is given*

Firmagon is given as an injection under the skin (subcutaneously), usually near your stomach. The site of injection is likely to vary.

#### *How often it is given*

Firmagon is usually given every month. Always remind your doctor or nurse to set up an appointment for your next injection.

#### *Overdose*

**As Firmagon is given to you under the supervision of your doctor, it is very unlikely that you will receive too much. However, if you experience any side effects after being given Firmagon, tell your doctor immediately or go to Accident and Emergency at your nearest hospital.** You may need urgent medical attention.

### While you are using Firmagon

#### *Things you must do*

**Be sure to keep all your doctor's appointments so your progress can be checked.**

Your doctor may want to check your blood pressure and do some blood and other tests from time to time to check on your progress and detect any unwanted side effects.

#### **Keep follow-up appointments with your doctor.**

It is important to have your follow-up doses of Firmagon at the appropriate times to get the best effects from your treatments.

If you believe your monthly dose of Firmagon has been forgotten, please talk to your doctor or nurse.

**If you feel that your medicine is not helping your condition, talk to your doctor.**

**Tell any other doctors, dentists, and pharmacists who are treating you that you are taking Firmagon.**

**If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking Firmagon.**

#### *Things to be careful of*

**When you are driving or operating machinery you need to know how Firmagon affects you.**

There are no known effects on the ability to drive or use machinery.

**If Firmagon makes you feel dizzy or light-headed, be careful when getting up from a sitting or lying position.**

These are signs of low blood pressure.

### Side effects

**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Firmagon.**

All medicines can have side effects. Sometimes they are serious, most of the time they are not. Side effects may happen at the start of treatment or they may happen after you have been taking your medicine for some time. You may need medical treatment if you get some of the side effects.

**If you get any side effects, do not stop taking Firmagon without first talking to your doctor or pharmacist.**

**Ask your doctor or pharmacist to answer any questions you may have.**

**Tell your doctor if you notice any of the following and they worry you:**

- hot flushes
- injection site pain and redness
- trouble sleeping
- dizziness
- headache
- nausea
- constipation
- night sweats
- chills
- fever
- weakness
- tiredness
- increased weight
- erection problems
- loss of libido.

These side effects are usually mild.

These are the more common side effects of Firmagon. (Mostly these are mild and short-lived.)

**Tell your doctor or pharmacist if you notice anything that is making you feel unwell.**

Other side effects not listed above may happen in some people. Some of these side effects can only be found when your doctor does tests from time to time to check your progress.

**Do not be alarmed by this list of possible side effects.**

You may not experience any of them.

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## After using Firmagon

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### *Storage*

Firmagon is usually stored in the doctor's surgery or clinic, or at the pharmacy. However, if you need to store Firmagon:

**Keep your medicine in a cool dry place where the temperature stays below 25°C.**

**Keep your medicine where children cannot reach it.**

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

**Keep Firmagon in the original container until it is time to take it / for it to be given.**

If you take your medicine out of the original container, it will not keep well.

**Do not store Firmagon or any other medicine in the bathroom or near a sink.**

**Do not leave it on a window sill or in the car on hot days.**

Heat and dampness can destroy some medicines.

Do not use Firmagon after the expiry date printed on the vials and outer packaging. The expiry date refers to the last day of that month.

After reconstitution the product should be injected immediately.

### *Disposal*

**If your doctor tells you to stop treatment with Firmagon or it has passed its expiry date, ask your pharmacist what to do with any medicine that is left over.**

Firmagon 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.

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## Product description

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### *What it looks like*

Firmagon is a white to off-white powder for injection (powder and solvent for injection).

**Starter dose - 1 pack contains:**

- 2 vials each containing 120 mg powder and 2 pre-filled syringes each containing 3mL solvent (sterile water)
- 2 vial adapters, 2 plunger rods and 2 safety injection needles

**Maintenance dose - 1 pack contains:**

- 1 vial containing 80 mg powder and 1 pre-filled syringe with 4.2mL solvent (sterile water)
- 1 vial adapter, 1 plunger rod and 1 safety injection needle

### *Ingredients*

The active substance:

- degarelix (as acetate) 80 mg or 120 mg

Other ingredients:

- mannitol

The solvent:

- water for injection (sterile water).

### *Sponsor*

**Ferring Pharmaceuticals Pty Ltd**

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FIRMAGON® 120 mg Powder and Solvent for Injection, depot AUST R 200046

FIRMAGON® 80 mg Powder and Solvent for Injection, depot AUST R 200047

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