

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I using FIRMAGON?

FIRMAGON contains the active ingredient degarelix (as acetate), which is a synthetic hormone that reduces the level of the male hormone, testosterone. It is used to treat prostate cancer and it may slow or stop the growth of the cancer.

For more information, see Section [1. Why am I using FIRMAGON?](#) in the full CMI.

### 2. What should I know before I use FIRMAGON?

Do not use FIRMAGON if you have ever had an allergic reaction to degarelix or to any of the ingredients listed at the end of the CMI, see Section [7. Product details](#).

**Talk to your doctor if you have any other medical conditions or take any other medicines.**

For more information, see Section [2. What should I know before I use FIRMAGON?](#) in the full CMI.

### 3. What if I am taking other medicines?

FIRMAGON might interfere with some medicines and affect how they work.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use FIRMAGON?

- FIRMAGON is given every month. It will be given to you by your doctor or nurse.
- It is given as an injection deep under the skin (subcutaneously) in your belly area.

More instructions can be found in Section [4. How do I use FIRMAGON?](#) in the full CMI and in the 'Instructions for Use' leaflet inside the carton.

### 5. What should I know while using FIRMAGON?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using FIRMAGON.</li><li>• Be sure to keep all your doctor's appointments so your progress can be checked.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• If you get any side effects, do not stop using FIRMAGON, without first talking to your doctor or pharmacist.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• There are no known effects on the ability to drive or use machinery.</li><li>• If you feel dizzy or light-headed while you are receiving FIRMAGON, be careful when getting up from a sitting or lying position. These are signs of low blood pressure.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Store it in a cool dry place, where the temperature stays below 25°C, away from heat or sunlight.</li><li>• Always store FIRMAGON in the original container until it is time for it to be given.</li></ul>

For more information, see Section [5. What should I know while using FIRMAGON?](#) in the full CMI.

### 6. Are there any side effects?

All medicines can have side effects. Most of them are minor and temporary but some may need medical attention.

**Tell your doctor if you experience any side effects that bother you. If in the period after a FIRMAGON injection you experience 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, seek urgent medical attention, as you may be having a serious allergic reaction to the medicine.**

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# FIRMAGON®

Active ingredient: *degarelix (as acetate)*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using FIRMAGON. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using FIRMAGON.**

Where to find information in this leaflet:

- [1. Why am I using FIRMAGON?](#)
- [2. What should I know before I use FIRMAGON?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use FIRMAGON?](#)
- [5. What should I know while using FIRMAGON?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

### 1. Why am I using FIRMAGON?

FIRMAGON contains the active ingredient degarelix (as acetate), which is a synthetic hormone that reduces the level of the male androgenic hormone testosterone. As such, FIRMAGON is a form of androgen deprivation therapy (ADT).

FIRMAGON is a gonadotrophin releasing hormone (GnRH) antagonist (blocker) used to treat prostate cancer. FIRMAGON may slow or stop the growth of the cancer.

**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.

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

### 2. What should I know before I use FIRMAGON?

#### Warnings

**Do not use FIRMAGON if:**

- you are allergic to degarelix (as acetate), or any similar drugs known as GnRH antagonists (blockers) or allergic to any of the ingredients listed at the end of this leaflet.
- you are a woman or a child.
- the expiry date printed on the pack has passed
- the packaging is torn or shows signs of tampering

Always check the ingredients to make sure you can use this medicine.

**Check with your doctor if you:**

- have any other medical conditions especially the following:
  - heart problems, including angina (non-compensated cardiac insufficiency, angina) and cardiac arrhythmias (irregular heartbeats). including in patients receiving some medicines that can cause arrhythmias
  - high blood pressure (hypertension)
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects.

It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

### 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

**If you are being treated for heart rhythm problems, speak to your doctor about the need to monitor your condition and treatment more closely. The risk of heart rhythm problems may be increased when using FIRMAGON. FIRMAGON might interfere with some medicines which include:**

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

Your doctor will advise you if you have to change any medicine while on FIRMAGON.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if they are affected by FIRMAGON.**

### 4. How do I use FIRMAGON?

#### How much to use

- Two injections of 120 mg are given as a first dose (starting dose - total of 240 mg). For all subsequent doses one injection of 80 mg (maintenance dose) is given every month.
- FIRMAGON injections will be given to you by a doctor or nurse. Instructions for proper use of the drug are included in the package insert.

#### When to use FIRMAGON

- FIRMAGON is usually given every month.
- The starting dose (240 mg total) is followed one month later by the first maintenance dose (80 mg).
- Subsequent maintenance doses are usually given every month thereafter.

Always remind your doctor or nurse to set up an appointment for your next injection. If you are unable to make the appointment for your next FIRMAGON dose, be sure to inform your doctor or nurse.

#### How to use FIRMAGON

**FIRMAGON is given as an injection deep under the skin (subcutaneously) in your belly area.**

FIRMAGON injections will be prepared and given to you by your doctor or a nurse.

The injected liquid forms a depot (a gel-like bubble) under the skin from which a continuous release of degarelix takes place over a period of a month.

For this reason, FIRMAGON should not be injected in areas of the belly exposed to pressure e.g. not under a belt-line or waistband, and not close to the ribs.

The injection site should not be rubbed or massaged as this might alter the release of degarelix from the depot that forms under the skin

#### **If you use too much FIRMAGON**

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 think that you have used too much FIRMAGON or experience any side effects after being given FIRMAGON, you may need urgent medical attention.

#### **You should immediately:**

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## **5. What should I know while using FIRMAGON?**

### **Things you should 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 tests 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 treatment.

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.**

Remind any doctor, dentist or pharmacist you visit that you are using FIRMAGON.

### **Things you should not do**

- If you get any side effects, do not stop using FIRMAGON, without first talking to your doctor or pharmacist.

### **Driving or using machines**

**Be careful before you drive or use any machines or tools until you know how FIRMAGON affects you.**

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

**If you feel dizzy or light-headed while you are receiving FIRMAGON, be careful when getting up from a sitting or lying position.**

These might be signs of low blood pressure.

### **Looking after your medicine**

FIRMAGON is usually stored in the doctor's surgery or clinic, or at the pharmacy. However, if you need to store FIRMAGON before your next dose:

**Store it in a cool dry place, where the temperature stays below 25°C, away from heat or sunlight.**

For example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Heat and dampness can destroy some medicines.

Follow the instructions in the carton on how to take care of your medicine properly.

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

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

**Keep it where young children cannot reach it.**

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

After reconstitution the product should be injected immediately.

### **Getting rid of any unwanted medicine**

**If you are storing FIRMAGON at home and your doctor stops your treatment with FIRMAGON or it has passed its expiry date, ask your pharmacist what to do with any medicine that is unused.** FIRMAGON should not be disposed of via wastewater or household waste.

These measures will help to protect the environment.

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

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

## **6. Are there any side effects?**

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### **Side effects**

Side effects	What to do
<b>Very common side effects (affect more than 1 in 10 users):</b> <ul style="list-style-type: none"><li>• injection site pain and redness</li><li>• hot flushes</li></ul> <b>Common side effects (affect more than 1 in 100 users):</b> <ul style="list-style-type: none"><li>• trouble sleeping</li><li>• dizziness</li><li>• headache</li><li>• nausea</li></ul>	<b>These side effects are not usually serious but can become serious.</b>  <b>Speak to your doctor if you have any of these side</b>

Side effects	What to do
<ul style="list-style-type: none"> <li>constipation</li> <li>night sweats</li> <li>chills</li> <li>fever</li> <li>weakness</li> <li>tiredness</li> <li>increased weight</li> </ul> <p><b>Erectile dysfunction and loss of libido are common adverse events associated with androgen deprivation therapy.</b></p>	<p><b>effects and they bother or worry you.</b></p>

#### Serious side effects

Serious side effects	What to do
<p><b>Hypersensitivity or allergic reactions (uncommon side effects - affect less than 1 in 100 users):</b></p> <ul style="list-style-type: none"> <li>shortness of breath, wheezing or difficulty breathing</li> <li>swelling of the face, lips, tongue or other parts of the body</li> <li>rash, itching or hives on the skin</li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

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

Other side effects not listed here may occur 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.

#### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

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

#### What FIRMAGON contains

<b>Active ingredient (main ingredient)</b>	degarelix (as acetate)
<b>Other ingredients (inactive ingredients)</b>	<p><i>Powder:</i></p> <p>mannitol</p> <p><i>Solvent:</i></p> <p>water for injections (sterile water)</p>

**FIRMAGON 80 mg:** Contains degarelix (as acetate) 80 mg.

**FIRMAGON 120 mg:** Contains degarelix (as acetate) 120 mg.

**Do not use this medicine if you are allergic to any of these ingredients.**

#### What FIRMAGON looks like

FIRMAGON is a white to off-white powder (powder for injection) and clear and colourless solvent (solvent for injection)

#### Starter dose (FIRMAGON 120 mg) - 1 pack contains:

2 clear glass vials with rubber stoppers and flip off seals each containing 120 mg degarelix (as powder) and 2 clear glass pre-filled syringes with rubber plunger stoppers and rubber tip caps each containing 3 mL solvent (water for injections)

2 vial adapters, 2 plunger rods and 2 safety injection needles (AUST R 200046)

#### Maintenance dose (FIRMAGON 80 mg) - 1 pack contains:

1 clear glass vial with a rubber stopper and flip off seal containing 80 mg degarelix (as powder) and 1 clear glass pre-filled syringe with a rubber plunger stopper and rubber tip cap with line marking at 4 mL containing 4.2 mL solvent (water for injections)

1 vial adapter, 1 plunger rod and 1 safety injection needle (AUST R 200047)

#### Who distributes FIRMAGON

Ferring Pharmaceuticals Pty Ltd

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20 Bridge Street

Pymble 2073 NSW

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