

Package leaflet: Information for the user  
**FIRMAGON® 80 mg powder and solvent for solution for injection**  
degarelix

The name of your medicine is FIRMAGON® 80 mg powder and solvent for solution for injection, however, it will be referred to as FIRMAGON throughout this leaflet.

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet:**

1. What FIRMAGON is and what it is used for
2. What you need to know before you use FIRMAGON
3. How to use FIRMAGON
4. Possible side effects
5. How to store FIRMAGON
6. Contents of the pack and other information

**1. WHAT FIRMAGON IS AND WHAT IT IS USED FOR**

FIRMAGON contains degarelix.

Degarelix is a synthetic hormone blocker used in the treatment of prostate cancer and for the treatment of high-risk prostate cancer prior to radiotherapy and in combination with radiotherapy in adult male patients. Degarelix mimics a natural hormone (gonadotrophin-releasing hormone, GnRH) and directly blocks its effects. By doing so, degarelix immediately reduces the level of the male hormone testosterone that stimulates the prostate cancer.

**2. WHAT YOU NEED TO KNOW BEFORE YOU USE FIRMAGON**

**Do not use FIRMAGON**

If you are allergic to degarelix or any of the other ingredients of this medicine (listed in section 6).

**Warnings and precautions**

Please tell your doctor if you have any of the following:

- Any cardiovascular conditions or heart rhythm problems (arrhythmia), or are being treated with medicines for this condition. The risk of heart rhythm problems may be increased when using FIRMAGON.
- Diabetes mellitus. Worsening or onset of diabetes may occur. If you have diabetes, you may have to measure blood glucose more frequently.
- Liver disease. Liver function may need to be monitored.
- Kidney disease. Use of FIRMAGON has not been investigated in patients with severe kidney disease.
- Osteoporosis or any condition that affects the strength of your bones. Reduced level of testosterone may cause a reduction in bone calcium (thinning of bones).
- Severe hypersensitivity. Use of FIRMAGON has not been investigated in patients with severe hypersensitivity reactions.

**Children and adolescents**

Do not give this medicine to children or adolescents.

**Other medicines and FIRMAGON**

FIRMAGON might interfere with some medicines used to treat heart rhythm problems (e.g. quinidine, procainamide, amiodarone and sotalol) or other medicines which can have an effect on heart rhythm (e.g. methadone (used for pain relief and as part of drug addiction detoxification), moxifloxacin (an antibiotic), antipsychotics).

Tell your doctor if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

**Driving and using machines**

Tiredness and dizziness are common side effects that may impair your ability to drive and use machines. These side effects may be due to the treatment or effects resulting from the underlying disease.

**3. HOW TO USE FIRMAGON**

This medicine is usually injected by a nurse or a doctor.

The recommended starting dose is two consecutive injections of 120 mg. After that, you will receive a monthly 80 mg injection. The injected liquid forms a gel from which degarelix is released over a period of one month.

FIRMAGON must be injected under the skin (subcutaneously) ONLY. FIRMAGON must NOT be given into a blood vessel (intravenously). Precautions must be taken to avoid accidental injection into a vein. The site of injection is likely to vary within the abdominal region.

**If you forget to use FIRMAGON**

If you believe your monthly dose of FIRMAGON has been forgotten, please talk to your doctor. If you have any further questions on the use of this medicine, ask your doctor.

**4. POSSIBLE SIDE EFFECTS**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

A very serious allergic reaction to this medicine is rare. Seek medical advice straight away if you develop a severe rash, itching or shortness of breath or difficulty breathing. These could be symptoms of a severe allergic reaction.

**Very common (may affect more than 1 in 10 people)**

Hot flushes, injection site pain and redness. Side effects at the injection site are most common with the starting dose and less common with the maintenance dose.

**Common (may affect up to 1 in 10 people)**

- injection site swelling, node and hardness
- chills, fever or influenza-like illness after the injection
- trouble sleeping, tiredness, dizziness, headache
- increased weight, nausea, diarrhoea, elevated levels of some liver enzymes
- excessive sweating (including night sweats), rash
- anaemia
- musculoskeletal pain and discomfort
- reduced size of testicles, breast swelling, impotence

**Uncommon (may affect up to 1 in 100 people)**

- loss of sexual desire, testicular pain, pelvic pain, ejaculation failure, genital irritation, breast pain
- depression, mental impairment
- skin redness, loss of hair, skin nodule, numbness
- allergic reactions, hives, itching
- decreased appetite, constipation, vomiting, dry mouth, abdominal pain and discomfort, increased blood sugar/diabetes mellitus, increased cholesterol, changes in blood calcium, decreased weight

- high blood pressure, changes in heart rhythm, changes in ECG (QT-prolongation), feeling of abnormal heart beat, dyspnoea, peripheral oedema
- muscular weakness, muscle spasms, joint swelling/stiffness, osteoporosis/osteopenia, pain in the joint
- frequent urination, urinary urgency (must hurry to pass urine), difficult or painful urination, urination at night, impaired renal function, incontinence
- blurred vision
- discomfort at injection including decreased blood pressure and heart rate (vasovagal reaction)
- malaise

**Rare (may affect up to 1 in 1,000 people)**

- febrile neutropenia (very low number of white blood cell in combination with fever), heart attack, heart failure
- unexplained muscular pain or cramps, tenderness, or weakness. The muscle problems can be serious, including muscle breakdown resulting in kidney damage.

**Very rare (may affect up to 1 in 10,000 people)**  
injection site infection, abscess and necrosis

**Reporting of side effects**

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard). By reporting side effects you can help provide more information on the safety of this medicine.

**5. HOW TO STORE FIRMAGON**

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the vials, syringes and outer packaging. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

**After reconstitution:**

This medicine is stable for 2 hours at 25°C. Due to the risk of microbial contamination, this medicine should be used immediately. If not used immediately, the use of this medicine are the responsibility of the user.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

If your medicine becomes discoloured or shows any signs of deterioration consult your pharmacist who will advise you what to do.

**6. CONTENTS OF THE PACK AND OTHER INFORMATION**

**What FIRMAGON contains**

- The active substance is degarelix, each vial contains 80 mg degarelix (as acetate). After reconstitution 1 ml of the reconstituted solution contains 20 mg degarelix.
- The other ingredient of the powder is mannitol (E421).
- The solvent is water for injections.

**What FIRMAGON looks like and contents of the pack**

FIRMAGON is a powder and solvent for solution for injection. The powder is white to off-white. The solvent is a clear, colourless solution.

Pack-size of 1 tray containing:  
1 vial with powder containing 80 mg of degarelix and 1 pre-filled syringe with 4.2 ml of solvent.

1 plunger rod, 1 vial adapter and 1 injection needle. Manufactured by Ferring GmbH, Wittland 11, Kiel, D-24109, Germany. Procured from within the EU and repackaged in the UK by the Parallel Import Product Licence holder: CD Pharma Ltd, 4 Cairn Court, East Kilbride, G74 4NB.

**FIRMAGON® 80 mg powder and solvent for solution for injection**  
**PL: 20492/0714**

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FIRMAGON is a registered trademark.

Date of preparation: 24<sup>th</sup> January 2025

**Blind or partially sighted? Is this leaflet hard to see or read? Call 01355 204 448 to obtain a leaflet in a format suitable for you.**

The following information is intended for healthcare professionals only:

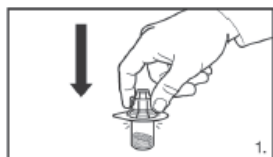
#### Instructions for proper use

#### NOTE:

- **DO NOT SHAKE THE VIALS**

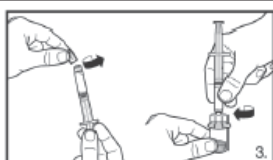
The pack contains one vial of powder and one pre-filled syringe with solvent that must be prepared for subcutaneous injection.

\* Chemical and physical in-use stability has been demonstrated for 2 hours at 25°C. From a microbiological point of view, unless the method of reconstitution precludes the risk of microbial contamination, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user.

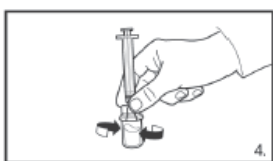


1. Remove the cover from the vial adapter pack. Attach the adapter to the powder vial by pressing the adapter down until the spike pushes through the rubber stopper and the adapter snaps in place.

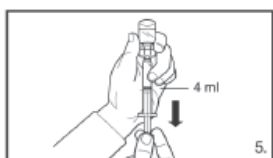
2. Prepare the pre-filled syringe by attaching the plunger rod.



3. Remove the cap of the pre-filled syringe. Attach the syringe to the powder vial by screwing it on to the adapter. **Transfer all solvent to the powder vial.**



4. With the syringe still attached to the adapter, swirl gently until the liquid looks clear and without undissolved powder or particles. If the powder adheres to the side of the vial above the liquid surface, the vial can be tilted slightly. **Avoid shaking to prevent foam formation.**  
A ring of small air bubbles on the surface of the liquid is acceptable. The reconstitution procedure usually takes a few minutes, but may take up to 15 minutes in some cases.



5. Turn the vial upside down and draw up to the line mark on the syringe for injection. **Always make sure to withdraw the precise volume** and adjust for any air bubbles.

6. Detach the syringe from the vial adapter and attach the needle for deep subcutaneous injection to the syringe.



7. Perform a deep subcutaneous injection. To do so: grasp the skin of the abdomen, elevate the subcutaneous tissue and insert the needle deeply at an angle of **not less than 45 degrees**.  
Inject **4 ml of FIRMAGON 80 mg slowly**, immediately after reconstitution.\*

8. No injections should be given in areas where the patient will be exposed to pressure, e.g. around the belt or waistband or close to the ribs.  
Do not inject directly into a vein. Gently pull back the plunger to check if blood is aspirated. If blood appears in the syringe, the medicinal product can no longer be used. Discontinue the procedure and discard the syringe and the needle (reconstitute a new dose for the patient).

**Package leaflet: Information for the user**  
**Degarelix Ferring 80 mg powder**  
**and solvent for solution for**  
**injection**  
degarelix

The name of your medicine is Degarelix Ferring 80 mg powder and solvent for solution for injection, however, it will be referred to as Degarelix Ferring throughout this leaflet.

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet:**

1. What Degarelix Ferring is and what it is used for
2. What you need to know before you use Degarelix Ferring
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6. Contents of the pack and other information

**1. WHAT DEGARELIX FERRING IS AND WHAT IT IS USED FOR**

Degarelix Ferring contains degarelix. Degarelix is a synthetic hormone blocker used in the treatment of prostate cancer and for the treatment of high-risk prostate cancer prior to radiotherapy and in combination with radiotherapy in adult male patients. Degarelix mimics a natural hormone (gonadotrophin-releasing hormone, GnRH) and directly blocks its effects. By doing so, degarelix immediately reduces the level of the male hormone testosterone that stimulates the prostate cancer.

**2. WHAT YOU NEED TO KNOW BEFORE YOU USE DEGARELIX FERRING**

**Do not use Degarelix Ferring**

If you are allergic to degarelix or any of the other ingredients of this medicine (listed in section 6).

**Warnings and precautions**

Please tell your doctor if you have any of the following:

- Any cardiovascular conditions or heart rhythm problems (arrhythmia), or are being treated with medicines for this condition. The risk of heart rhythm problems may be increased when using Degarelix Ferring.
- Diabetes mellitus. Worsening or onset of diabetes may occur. If you have diabetes, you may have to measure blood glucose more frequently.
- Liver disease. Liver function may need to be monitored.
- Kidney disease. Use of Degarelix Ferring has not been investigated in patients with severe kidney disease.
- Osteoporosis or any condition that affects the strength of your bones. Reduced level of testosterone may cause a reduction in bone calcium (thinning of bones).
- Severe hypersensitivity. Use of Degarelix Ferring has not been investigated in patients with severe hypersensitivity reactions.

**Children and adolescents**

Do not give this medicine to children or adolescents.

**Other medicines and Degarelix Ferring**

Degarelix Ferring might interfere with some medicines used to treat heart rhythm problems (e.g. quinidine, procainamide, amiodarone and sotalol) or other medicines which can have an effect on heart rhythm (e.g. methadone (used for pain relief and as part of drug addiction detoxification), moxifloxacin (an antibiotic), antipsychotics).

Tell your doctor if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

**Driving and using machines**

Tiredness and dizziness are common side effects that may impair your ability to drive and use machines. These side effects may be due to the treatment or effects resulting from the underlying disease.

**3. HOW TO USE DEGARELIX FERRING**

This medicine is usually injected by a nurse or a doctor.

The recommended starting dose is two consecutive injections of 120 mg. After that, you will receive a monthly 80 mg injection. The injected liquid forms a gel from which degarelix is released over a period of one month.

Degarelix Ferring must be injected under the skin (subcutaneously) ONLY. Degarelix Ferring must NOT be given into a blood vessel (intravenously). Precautions must be taken to avoid accidental injection into a vein. The site of injection is likely to vary within the abdominal region.

**If you forget to use Degarelix Ferring**

If you believe your monthly dose of Degarelix Ferring has been forgotten, please talk to your doctor.

If you have any further questions on the use of this medicine, ask your doctor.

**4. POSSIBLE SIDE EFFECTS**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

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**Very common (may affect more than 1 in 10 people)**

Hot flushes, injection site pain and redness. Side effects at the injection site are most common with the starting dose and less common with the maintenance dose.

**Common (may affect up to 1 in 10 people)**

- injection site swelling, node and hardness
- chills, fever or influenza-like illness after the injection
- trouble sleeping, tiredness, dizziness, headache
- increased weight, nausea, diarrhoea, elevated levels of some liver enzymes
- excessive sweating (including night sweats), rash
- anaemia
- musculoskeletal pain and discomfort
- reduced size of testicles, breast swelling, impotence

**Uncommon (may affect up to 1 in 100 people)**

- loss of sexual desire, testicular pain, pelvic pain, ejaculation failure, genital irritation, breast pain
- depression, mental impairment
- skin redness, loss of hair, skin nodule, numbness
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- decreased appetite, constipation, vomiting, dry mouth, abdominal pain and discomfort, increased blood sugar/diabetes mellitus, increased cholesterol, changes in blood calcium, decreased weight

- high blood pressure, changes in heart rhythm, changes in ECG (QT-prolongation), feeling of abnormal heart beat, dyspnoea, peripheral oedema
- muscular weakness, muscle spasms, joint swelling/stiffness, osteoporosis/osteopenia, pain in the joint
- frequent urination, urinary urgency (must hurry to pass urine), difficult or painful urination, urination at night, impaired renal function, incontinence
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injection site infection, abscess and necrosis

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**5. HOW TO STORE DEGARELIX FERRING**

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the vials, syringes and outer packaging. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

**After reconstitution:**

This medicine is stable for 2 hours at 25°C. Due to the risk of microbial contamination, this medicine should be used immediately. If not used immediately, the use of this medicine are the responsibility of the user.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

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- The other ingredient of the powder is mannitol (E421).
- The solvent is water for injections.

**What Degarelix Ferring looks like and contents of the pack**

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Pack-size of 1 tray containing:  
1 vial with powder containing 80 mg of degarelix and 1 pre-filled syringe with 4.2 ml of solvent.

1 plunger rod, 1 vial adapter and 1 injection needle. Manufactured by Ferring GmbH, Wittland 11, Kiel, D-24109, Germany. Procured from within the EU and repackaged in the UK by the Parallel Import Product Licence holder: CD Pharma Ltd, 4 Cairn Court, East Kilbride, G74 4NB.

**Degarelix Ferring 80 mg powder and solvent for solution for injection**      **PL: 20492/0714**

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Date of preparation: 24<sup>th</sup> January 2025

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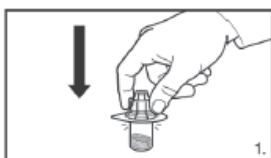
### Instructions for proper use

#### NOTE:

- **DO NOT SHAKE THE VIALS**

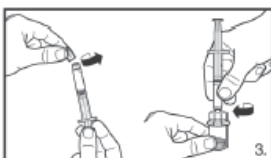
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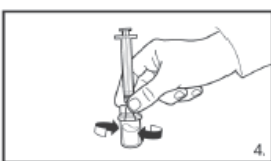


1. Remove the cover from the vial adapter pack. Attach the adapter to the powder vial by pressing the adapter down until the spike pushes through the rubber stopper and the adapter snaps in place.

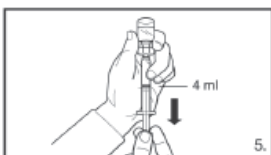
2. Prepare the pre-filled syringe by attaching the plunger rod.



3. Remove the cap of the pre-filled syringe. Attach the syringe to the powder vial by screwing it on to the adapter. **Transfer all solvent to the powder vial.**



4. With the syringe still attached to the adapter, swirl gently until the liquid looks clear and without undissolved powder or particles. If the powder adheres to the side of the vial above the liquid surface, the vial can be tilted slightly. **Avoid shaking to prevent foam formation.**  
A ring of small air bubbles on the surface of the liquid is acceptable. The reconstitution procedure usually takes a few minutes, but may take up to 15 minutes in some cases.



5. Turn the vial upside down and draw up to the line mark on the syringe for injection. **Always make sure to withdraw the precise volume** and adjust for any air bubbles.

6. Detach the syringe from the vial adapter and attach the needle for deep subcutaneous injection to the syringe.



7. Perform a deep subcutaneous injection. To do so: grasp the skin of the abdomen, elevate the subcutaneous tissue and insert the needle deeply at an angle of **not less than 45 degrees**.  
Inject **4 ml of Degarelix Ferring 80 mg slowly**, immediately after reconstitution.\*

8. No injections should be given in areas where the patient will be exposed to pressure, e.g. around the belt or waistband or close to the ribs.  
Do not inject directly into a vein. Gently pull back the plunger to check if blood is aspirated. If blood appears in the syringe, the medicinal product can no longer be used. Discontinue the procedure and discard the syringe and the needle (reconstitute a new dose for the patient).