Package leaflet: Information for the user

FERRING PHARMACEUTICALS

FIRMAGON® 120 mg

Powder and solvent for solution for injection

degarelix

Read all of this leaflet carefully before you start using 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 of the 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

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-relasing 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 (arrythmia), 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 strenght 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 of the 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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard

Ireland
HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2.
Tel: +353 1 6764971; Fax: +353 1 6762517; Website: www.hpra.ie;
E-mail: medsafety@hpra.ie

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 25ºC.
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.

6. Contents of the pack and other information

What FIRMAGON contains
- The active substance is degarelix. Each vial contains 120 mg degarelix (as acetate). After reconstitution 1 ml of the reconstituted solution contains 40 mg degarelix.
- The other ingredient of the powder is mannitol (E 421).
- 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 2 trays containing:
2 vials with powder containing 120 mg of degarelix and 2 pre-filled syringes with 3 ml of solvent.
2 plunger rods, 2 vial adapters and 2 injection needles.

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EU/1/08/504/001

Marketing Authorisation Holder in GB:
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United Kingdom
PLGB 03194/0128

Manufacturer
Ferring GmbH
Wittland 11
D-24109 Kiel
Germany

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

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Ferring Pharmaceuticals Ltd.
Tel: +44 844 931 0050
Contact2@ferring.com

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This leaflet was last revised in March 2022.

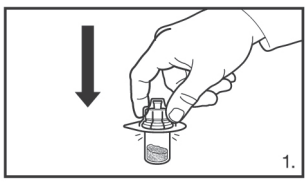
Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu/.

The following information is intended for healthcare professionals only:

Instructions for proper use

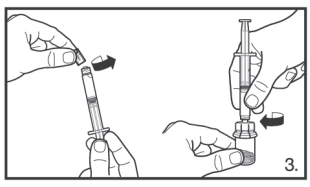
NOTE:
- **DO NOT SHAKE THE VIALS**

The pack contains two vials of powder and two pre-filled syringes with solvent that must be prepared for subcutaneous injection. Hence the procedure described below need to be repeated a second time.

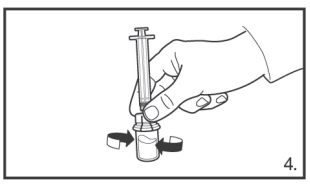


1. Remove the cover from the vial adapter pack. Attach the adapter to the powder vial by pressing the adapter down until the spike pushes through the rubber stopper and the adapter snaps in place.

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

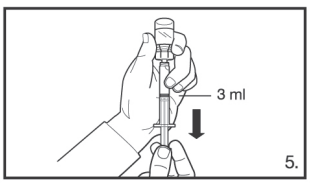


3. Remove the cap of the pre-filled syringe. Attach the syringe to the powder vial by screwing it on to the adapter.
Transfer all solvent to the powder vial.



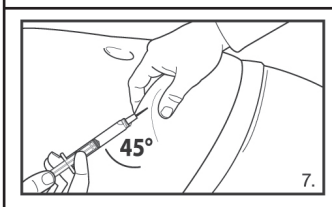
4. With the syringe still attached to the adapter, swirl gently until the liquid looks clear and without undissolved powder or particles. If the powder adheres to the side of the vial above the liquid surface, the vial can be tilted slightly.
Avoid shaking to prevent foam formation.

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 **3 ml of FIRMAGON 120 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).

9. Repeat the reconstitution procedure for the second dose. Choose a different injection site and **inject 3ml.**

- Chemical and physical in-use stability has been demonstrated for 2 hours at 25ºC. 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.

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