PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

FIRMAGON® 80 mg and 120 mg powder for solution for injection

Degarelix acetate

Contains sugar:

Each vial of FIRMAGON® 80 mg contains 220,5 mg mannitol

Each vial of FIRMAGON® 120 mg contains 160 mg mannitol

FIRMAGON® SOLVENT for solution for injection

Water for injection

Sugar free

Read all of this leaflet carefully before you are given FIRMAGON®

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or health care provider.
- FIRMAGON® has been prescribed for you personally and you should not share your medicine with other people.

  It may harm them, even if their symptoms are the same as yours.

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.

FIRMAGON® reduces the level of the male hormone, testosterone that stimulates the prostate cancer.

2. What you need to know before you use FIRMAGON®

FIRMAGON® should not be administered to you:

- if you are hypersensitive (allergic) to degarelix or to any of the other ingredients of FIRMAGON® (listed in section 6),
- if you are a woman,
- if you are a child,
- if you are pregnant,
- if you have a corrected QT (QT_C) duration of > 450 msec, for instance, if you are born with a prolonged QT interval,
- if you are currently taking or recently have taken medicine used to treat heart rhythm problems such as procainamide, quinidine, amiodarone and sotalol.

Warnings and precautions

Tell your doctor or health care provider before being given the injection:

- if you have any cardiovascular conditions or heart rhythm problems (dysrhythmias). The risk of heart rhythm problems may be increased when using FIRMAGON®,
- if you have liver disease. Liver function may need to be monitored,

- if you have kidney disease. Use of FIRMAGON® has not been investigated in patients with severe kidney disease,
- if you have a history of severe hypersensitivity, which includes severe allergic reaction characterized by raised, red, and itchy bumps and swelling of the face and eyes or severe untreated asthma,
- if you have bone density problems, such as 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),
- if you have diabetes mellitus (high blood sugar levels). Worsening or onset of diabetes may occur. If you have diabetes, you may have to measure your blood glucose more frequently.

Children and adolescents

Do not give FIRMAGON® to children or adolescents.

Other medicines and FIRMAGON®

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

FIRMAGON® may prolong the QTc interval therefore, FIRMAGON® should not be used with medicine known to prolong the QTc interval, such as medicine used to regulate your heart rhythm (e.g., quinidine, procainamide, amiodarone, and sotalol), methadone (used for pain relief), moxifloxacin (an antibiotic) or antipsychotics.

FIRMAGON® with food and drink

There is no special precaution for food and drink intake while using FIRMAGON®.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

FIRMAGON® must not be used in women.

FIRMAGON® may affect male fertility as long as the level of the male hormone, testosterone stay low.

Driving and using machines

There are no known effects on the ability to drive or use machinery. Tiredness and dizziness are common side effects that may impair your ability to drive and use machines.

It is not always possible to predict to what extent FIRMAGON® may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which FIRMAGON® affects them.

3. How to use FIRMAGON®

Do not share medicines prescribed for you with any other person.

You will not be expected to give yourself FIRMAGON®. It will be given to you by a person who is qualified to do so.

The powder and solvent are mixed and injected within 1 hour after mixing, by your doctor or a nurse, in your abdominal region. Instruction for proper use of the medicine is included in section 6 of this leaflet.

The appropriate dose will be injected under the skin (subcutaneously). The site of injection is likely to vary. The injected liquid forms a depot from which a continuous release of degarelix takes place over a period of one month.

The usual dose is as follow:

Initial dose: Two injections of 120 mg are given as a first dose.

Maintenance dose: For all subsequent doses one injection of 80 mg is given monthly.

Your doctor will tell you how long your treatment with FIRMAGON® will last. If you have the impression that the effect of FIRMAGON® is too strong or too weak, talk to your doctor or pharmacist.

If you received more FIRMAGON® than you should

Since a health care provider will administer FIRMAGON®, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forgot to use FIRMAGON®

Since a health care provider will administer FIRMAGON®, it is unlikely that the dose will be missed.

4. Possible side effects

FIRMAGON® can have side effects.

Not all side effects reported for FIRMAGON® are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using FIRMAGON®, please consult your health care provider for advice.

If any of the following happens, stop using FIRMAGON® and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have a serious reaction to FIRMAGON®. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- heart attack (chest discomfort, pain or discomfort in other areas of the upper body, and shortness of breath),
- heart failure (shortness of breath, swelling of the legs, ankles, feet, abdomen, tiredness and weakness, change in your heartbeat with persistent coughing or wheezing),
- neutropenic fever (very low number of white blood cell in combination with fever accompanied by chills, shaking and profuse sweating, weak and tired, pain and headaches).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Very common side effects:

- hot flushes,
- injection site pain, redness, swelling, node and hardness *,

  * Side effects at the injection site are very common with the starting dose and less common with the maintenance dose.

Common side effects:

- reduced number of red blood cells (anaemia),
- increased weight,
- trouble sleeping, dizziness, headache,
- nausea, diarrhoea,
- elevated levels of some liver enzymes (transaminases),
- excessive sweating, night sweats,
- discomfort or ache in the muscles, bones, or joints,

- impotence, reduced size of testicles, breast swelling,
- chills, fever,
- weakness, tiredness,
- influenza-like illness.

Uncommon side effects:

- allergic reactions,
- increase blood sugar, increase cholesterol, decreased weight, changes in the blood calcium, decreased appetite,
- loss of sexual desire,
- depression, mental impairment,
- reduced sensitivity to touch, temperature, or pain in a specific area of the body,
- blurred vision,
- changes in the way your heart beats, changes in ECG (QT-prolongation),
- high blood pressure,
- discomfort at injection including decreased blood pressure and heart rate (vasovagal reaction),
- difficulty or discomfort in breathing,
- dry mouth,
- abdominal pain and discomfort, constipation, vomiting,
- hives,
- locally changed skin colour, loss of hair,
- osteoporosis/osteopenia, pain in the joint, muscular weakness, muscle spasms, joint swelling/stiffness,
- frequent urination, urinary urgency (must hurry to pass urine), difficult or painful urination, urination at night, impaired renal function, incontinence (inability to control urination or defecation),

- testicular pain, pelvic pain or breast pain, genital irritation, ejaculation failure,
- malaise (a feeling of discomfort, unease, or weakness).

Rare side effects:

- unexplained muscular pain or cramps, tenderness, or weakness. The muscle problems can be serious, including muscle breakdown resulting in kidney damage.

Very rare side effects:

- serious injection site reactions such as injection site infection, injection site abscess or injection site necrosis that could require surgical treatment/drainage.

If you notice any side effects not mentioned in this leaflet, please inform you doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of FIRMAGON®.

5. How to store FIRMAGON®

- Store all medicine out of reach of children.
- Store at or below 25 ºC.
- FIRMAGON® should not be frozen.
- 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 is stable for 2 hours at 25 ºC. Due to the risk of microbial contamination, this medicine should be injected immediately.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What FIRMAGON® contains

The active ingredient is degarelix (as acetate).

The other ingredient is mannitol.

The solvent is water for injection.

The following information is intended for the health care provider only.

Instructions for proper use.

The instructions for reconstitution must be followed carefully.

Administration of other concentrations is not recommended because the gel depot formation is influenced by the concentration. The reconstituted solution should be a clear liquid, free of undissolved matter.

NOTE:

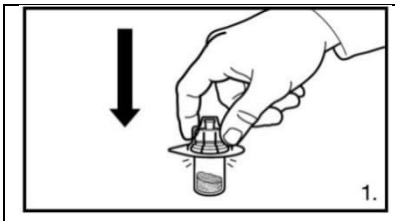
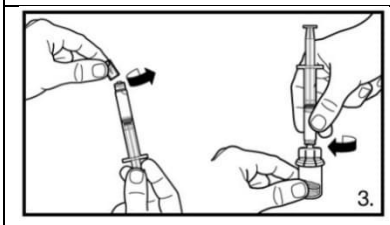
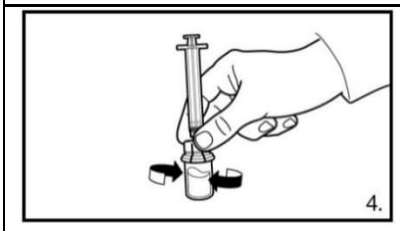
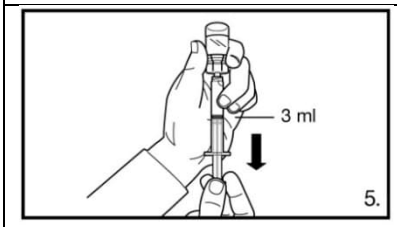
GLOVES SHOULD BE WORN DURING PREPARATION AND ADMINISTRATION

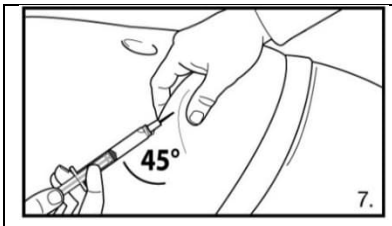
DO NOT SHAKE THE VIALS

FOLLOW ASEPTIC TECHNIQUE

FIRMAGON® 120 mg

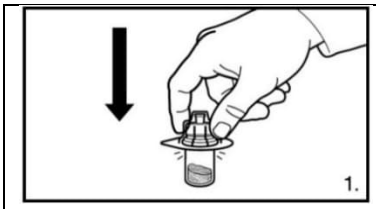
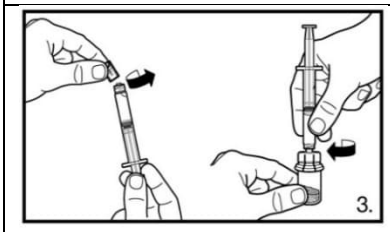
The pack contains two vials of powder and two pre-filled syringes with solvent that must be prepared for subcutaneous injection (s.c.). Hence, the procedure described below need to be repeated a second time.

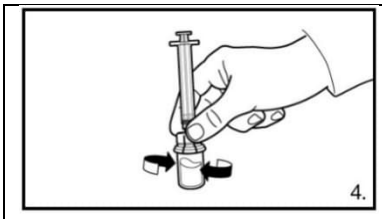
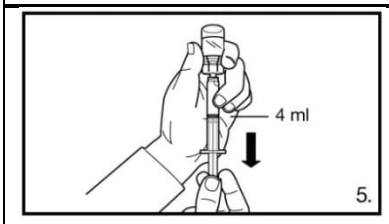
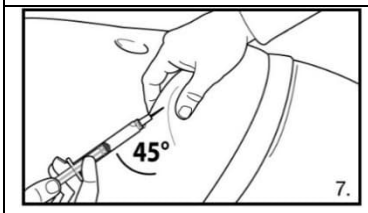
<table>
<tr><td>
</td><td>1. Remove the cover from the vial adapter pack. Attach the adapters to the powder vial by pressing the adapter down until the spike pushes through the rubber stopper and the adapter snaps in place.</td></tr>
<tr><td colspan="2">2. Prepare the pre-filled syringe by attaching the plunger rod.</td></tr>
<tr><td>
</td><td>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.</td></tr>
<tr><td>
</td><td>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.</td></tr>
<tr><td>
</td><td>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. Withdraw until the line marking at 3 ml.</td></tr>
<tr><td colspan="2">6. Detach the syringe from the vial adapter and attach the needle for deep s.c. injection to the syringe.</td></tr>
</table>

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

FIRMAGON® 80 mg

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

	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. **Withdraw until the line marking at 4 ml.**
6. Detach the syringe from the vial adapter and attach the needle for deep s.c. 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 product can no longer be used. Discontinue the procedure and discard the syringe and the needle (reconstitute a new dose for the patient).	

What FIRMAGON® looks like and the content of the pack

FIRMAGON® 120 mg: white to off-white lyophilisation cake.

FIRMAGON® 80 mg: white to off-white lyophilisation cake.

FIRMAGON® Solvent: clear, colourless solution.

FIRMAGON® 120 mg:

Starting dose – 1 pack contains:

2 vials with 120 mg powder. The vials are clear, colourless glass vials sealed with rubber-type stoppers and aluminium flip-off white seals.

2 pre-filled syringes with 3 ml of solvent. The pre-filled syringes are clear, colourless glass (type I) syringes with elastomer plunger stopper, tip cap and line-marking at 3 ml.

2 plunger rods, 2 vial adapters and 2 injection needles.

FIRMAGON® 80 mg:

Maintenance dose – 1 pack contains:

1 vial with 80 mg powder. The vial is a clear, colourless glass vial sealed with a rubber-type stopper and aluminium flip-off dark blue seal.

1 pre-filled syringe with 4,2 ml of solvent. The pre-filled syringe is a clear, colourless glass (type I) syringe with elastomer plunger stopper, tip cap and line-marking at 4 ml.

1 plunger rod, 1 vial adapter and 1 injection needle.

Maintenance dose – 3 pack contains:

3 x 1 vial with 80 mg powder. The vial is a clear, colourless glass vial sealed with a rubber-type stopper and aluminium flip-off dark blue seal.

3 x 1 pre-filled syringe with 4,2 ml solvent. The pre-filled syringe is a clear, colourless glass (type I) syringe with elastomer plunger stopper, tip cap and line-marking at 4 ml.

3 x 1 plunger rod, 3 x 1 vial adapter and 3 x 1 injection needle.

Holder of the Certificate of Registration

Ferring (Pty) Ltd.

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Tel no.: (012) 345 6358

This leaflet was last revised in

03 March 2025

Registration number

FIRMAGON® 120 mg: A43/21.12/0920

FIRMAGON® 80 mg: A43/21.12/0918

FIRMAGON® Solvent: A43/32.4/0919