FIRMAGON® (degarelix)

FOR THE TREATMENT OF ADULT MALE PATIENTS WITH ADVANCED HORMONE-DEPENDENT PROSTATE CANCER

A simple guide to dosing and administration

FIRMAGON® degarelix

START STRONG
STAY IN CONTROL

This guide is intended for healthcare professional use only

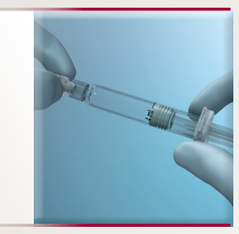
RECONSTITUTING FIRMAGON® 120mg OR 80mg

Step 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.

Step 2

- 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.**



Step 3

- 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.

Step 4

- 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.

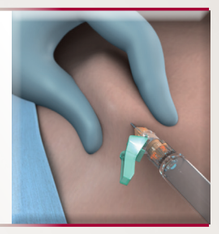
ADMINISTRATION OF FIRMAGON® 120mg OR 80mg

Step 5

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

Step 6

- 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**.



Step 7

- 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).

Step 8

- **Initiation dose:** Inject **3ml of FIRMAGON® 120mg** slowly, immediately after reconstitution*. **Repeat the reconstitution** procedure for the second dose. Choose a different injection site **and inject 3ml**.
- **Maintenance dose:** Inject a **single 4ml subcutaneous injection of FIRMAGON® 80mg** slowly, immediately after reconstitution*.

Important Note: The injection site in the abdominal region should vary. Injections should not be given in areas where the patient will be exposed to pressure – e.g. around the belt or waistband or close to the ribs.

*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.

Side effects at the injection site are reported mostly with the starting dose and less commonly with the maintenance dose. In the case of an injection site reaction, paracetamol or ibuprofen have been used to treat injection site symptoms. Patients have also used cooling measures, such as ice.

FIRMAGON®

STARTING DOSE — MAINTENANCE DOSES

Month 1	Month 2	Month 3	Month 4	Continue with maintenance dose for as long as treatment is required
240mg Injection (2x120mg)	80mg Injection	80mg Injection	80mg Injection	80mg Injection

STARTING DOSE

240mg

First month of treatment

240mg administered as TWO deep subcutaneous injections of 120mg each
(NB. 3 x 80mg injections are not equivalent)

First month of treatment

2 vials with **120mg** degarelix (powder);
2 pre-filled syringes with **3ml** solvent;
2 plunger rods; **2** vial adapters; **2** injection needles

Each STARTING DOSE vial contains 120mg degarelix (as acetate). After reconstitution, each ml of solution contains 40mg of degarelix

Each 120mg vial of Firmagon® should be reconstituted with **3ml** of the solvent supplied as per the instructions opposite and in the summary of product characteristics

Inject **3ml** of Firmagon® 120mg immediately after reconstitution*

Repeat this process to complete full initiation dose of 240mg

MAINTENANCE DOSE

80mg

Monthly administration from month 2 onwards
administered as ONE deep subcutaneous injection

Monthly administration

1 vial with **80mg** degarelix (powder);
1 pre-filled syringe with **4.2ml** solvent;
1 plunger rod; **1** vial adapter; **1** injection needle

Each MAINTENANCE DOSE vial contains 80mg degarelix (as acetate). After reconstitution, each ml of solution contains 20mg of degarelix

Each 80mg vial of Firmagon® should be reconstituted with **4.2ml** of the solvent supplied as per the instructions opposite and in the summary of product characteristics

Inject **4.0ml** of Firmagon® 80mg immediately after reconstitution*

Prescribing Information

Firmagon® (degarelix) 120mg and 80mg powder and solvent for solution for injection. **Please consult the full Summary of Product Characteristics before prescribing. Name of Product:** Firmagon 120mg and 80mg powder and solvent for solution for injection. **Composition:** Each vial contains 120mg or 80mg degarelix (as acetate). **Indication:** Firmagon is a gonadotrophin releasing hormone (GnRH) antagonist indicated for treatment of adult male patients with advanced hormone-dependent prostate cancer. **Dosage and administration:** For subcutaneous use only. Starting dose– 240mg administered as two subcutaneous injections of 120mg each. Maintenance dose – 80mg administered monthly as one subcutaneous injection. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients. **Special Warnings and Precautions:** Long-term androgen deprivation therapy may prolong the QT interval. The benefit/risk ratio must be thoroughly appraised in patients with a history of a corrected QT interval over 450 msec, in patients with a history of or risk factors for torsades de pointes and in patients receiving concomitant medicinal products that might prolong the QT interval as Firmagon has not been studied in these patients. A thorough QT study showed that there was no intrinsic effect of Firmagon on QT/QTc interval. Monitoring of liver function in patients with known or suspected hepatic disorder is advised during treatment. Firmagon has not been studied in patients with severe renal impairment, patients with a history of severe untreated asthma, anaphylactic reactions or severe urticaria, or angioedema. It can be anticipated that long periods of testosterone suppression in men will have effects on bone density. Diabetic patients may require more frequent monitoring of blood glucose when receiving androgen deprivation therapy. Cardiovascular disease such as stroke and myocardial infarction has been reported in the medical literature in patients with androgen deprivation therapy. Therefore, all cardiovascular risk factors should be taken into account. **Side effects:** Very Common: hot flush, injection site adverse reactions. Common: anaemia, weight increase, insomnia, dizziness, headache, diarrhoea, nausea, liver transaminases increased, hyperhidrosis (incl. night sweats), rash, musculoskeletal pain and discomfort, gynaecomastia, testicular atrophy, erectile dysfunction, chills, pyrexia, fatigue, Influenza-like illness. Uncommon: hypersensitivity, hyperglycemia/ diabetes mellitus, cholesterol increased, weight decreased, appetite decreased, changes in blood calcium, depression, libido decreased, mental impairment, hypoaesthesia, vision blurred, cardiac arrhythmia (incl. atrial fibrillation), palpitations, QT prolongation, hypertension, vasovagal reaction (incl. hypotension), dyspnoea, constipation, vomiting, abdominal pain, abdominal discomfort, dry mouth, bilirubin increased, alkaline phosphatase increased, urticaria, skin nodule, alopecia, pruritus, erythema, osteoporosis/osteopenia, arthralgia, muscular weakness, muscle spasms, joint swelling/stiffness, pollakiuria, micturition urgency, dysuria, nocturia, renal impairment, incontinence, testicular pain, breast pain, pelvic pain, genital irritation, ejaculation failure, malaise, peripheral oedema. Rare: neutropenic fever, anaphylactic reactions, myocardial infarction, cardiac failure. Please consult the full Summary of Product Characteristics for further information about side effects. **Presentation:** Firmagon 120mg contains 2 vials of 120mg powder for solution for injection and 2 solvent prefilled syringes, 2 vial adaptors and 2 administration needles. Firmagon 80mg contains 1 vial of 80mg powder for solution for injection and 1 solvent pre-filled syringe, 1 vial adaptor and administration needle. Solvent for both 120mg and 80mg: Water for injection. **Marketing Authorisation Number:** 80mg: EU/1/08/504/001, 120mg: EU/1/08/504/002. **Marketing Authorisation Holder:** Ferring Pharmaceuticals A/S, Kay Fiskers Plads 11, DK-2300 Copenhagen S, Denmark. **Legal category:** POM. **Basic NHS price:** Firmagon 120mg - £260.00; Firmagon 80mg - £129.37 **Date of preparation:** July 2018. Firmagon® is a registered trademark. **PI Job Code:** FN/1250/2018/UK(1).

Adverse events should be reported.
Reporting forms and information can be found at www.mhra.gov.uk/yellowcard.
Adverse events should also be reported to Ferring Pharmaceuticals Ltd. Tel: 0800 111 4126.
Email: medical@ferring.com

FERRING PHARMACEUTICALS

Job code: UK-FN-1900012 | Date of preparation: December 2019