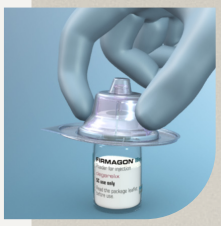
FIRMAGON® (degarelix)

FIRMAGON® is indicated for the treatment of adult male patients with advanced hormone-dependent prostate cancer, also in combination with radiotherapy and as neo-adjuvant treatment prior to radiotherapy in patients with high-risk localised or locally advanced hormone dependent prostate cancer.[1,2]

FIRMAGON®
degarelix
Think beyond the prostate

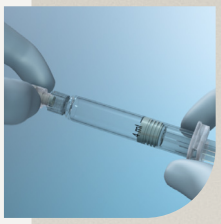
A simple guide to dosing and administration

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.

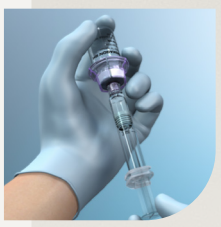


Step 2

- 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.



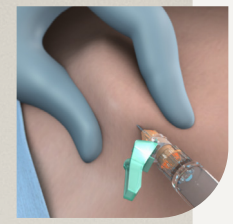
Step 4

- 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

- 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.
- 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.
- 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, discard the syringe and needle, and reconstitute a new dose for the patient.
- Leave the needle in for at least 30 seconds before a slow withdrawal.

Step 7

- The injection site in the abdominal region should vary.

Side effects

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.

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.

Month 1 — 240mg Injection (2x120mg)

Month 2 — 80mg Injection

Month 3 — 80mg Injection

Month 4 — 80mg Injection

Continue with maintenance dose for as long as treatment is required — 80mg Injection

MAINTENANCE DOSE: Inject a single 4ml subcutaneous injection of FIRMAGON® 80mg slowly, immediately after reconstitution*.

*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.

To watch a short video on how to reconstitute and administer FIRMAGON®, scan the QR code or visit the website: www.ferringukhub.co.uk/urology/firmagon

Prescribing Information: Firmagon® (degarelix) 120 mg and 80 mg powder and solvent for solution for injection. **Please consult the full Summary of Product Characteristics before prescribing. Name of Product:** Firmagon 120 mg and 80 mg powder and solvent for solution for injection. **Composition:** Each vial contains 120 mg or 80 mg 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, for treatment of high-risk localised and locally advanced hormone dependent prostate cancer in combination with radiotherapy, and as neo-adjuvant treatment prior to radiotherapy in patients with high-risk localised or locally advanced hormone dependent prostate cancer. **Dosage and administration:** For subcutaneous use only in the abdominal region. Starting dose – 240 mg administered as two subcutaneous injections of 120 mg each. Maintenance dose – 80 mg administered monthly as one subcutaneous injection. The first maintenance dose should be given one month after the starting dose. **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. **Interactions:** Medicinal products known to prolong the QTc interval or medicinal products able to induce torsades de points such as Class IA (e.g. quinidine, disopyramide) or Class III (e.g. amiodarone, sotalol, dofetilide, ibutilide) antiarrhythmic drugs, methadone, moxifloxacine, antipsychotics, etc. should be carefully evaluated. **Driving and using machines:** Common adverse reactions of fatigue and dizziness may influence the ability to drive and use machines. **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 120 mg contains 2 vials of 120 mg powder for solution for injection and 2 solvent prefilled syringes, 2 vial adaptors and 2 administration needles. Firmagon 80 mg contains 1 vial of 80 mg powder for solution for injection and 1 solvent pre-filled syringe, 1 vial adaptor and administration needle. Solvent for both 120 mg and 80 mg: Water for injection. **Marketing Authorisation Number:** 80 mg: 03194/0129, 120 mg: 03194/0128. **Marketing Authorisation Holder:** Ferring Pharmaceuticals A/S, Kay Fiskers P lads 11, DK-2300 Copenhagen S, Denmark. **Legal category:** POM. **Basic NHS price:** Firmagon 120 mg - £260.00; Firmagon 80 mg - £129.37 **Date of preparation:** October 2022 Firmagon® is a registered trademark. **PI Job Code:** UK-FN-220041

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.uk@ferring.com

References: 1. FIRMAGON® 120mg injection Summary of Product Characteristics. Ferring Pharmaceuticals Ltd. October 2022. Available at: https://www.medicines.org.uk/emc/product/6537. Last accessed: January 2023.
2. FIRMAGON® 80 mg injection Summary of Product Characteristics. Ferring Pharmaceuticals Ltd. October 2022. Available at: https://www.medicines.org.uk/emc/product/6535. Last accessed: January 2023.

Date of preparation: January 2023
UK-FN-2200054

FERRING PHARMACEUTICALS