Prescribing Information: Degarelix Ferring (degarelix acetate) 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:** Degarelix Ferring 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:** Degarelix Ferring 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 Degarelix Ferring has not been studied in these patients. A thorough QT study showed that there was no intrinsic effect of Degarelix Ferring on QT/QTc interval. Monitoring of liver function in patients with known or suspected hepatic disorder is advised during treatment. Degarelix Ferring 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:** Degarelix Ferring 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. Degarelix Ferring 80 mg contains 1 vial of 80 mg powder for solution for injection and 1 solvent prefilled 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 Plads 11, DK-2300 Copenhagen S, Denmark. **Legal category:** POM. **Basic NHS price:** Degarelix Ferring 120 mg - £157.90; Degarelix Ferring 80 mg - £79.90 **Date of preparation:** June 2025 **PI Job Code:** UK-FN-2500021

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