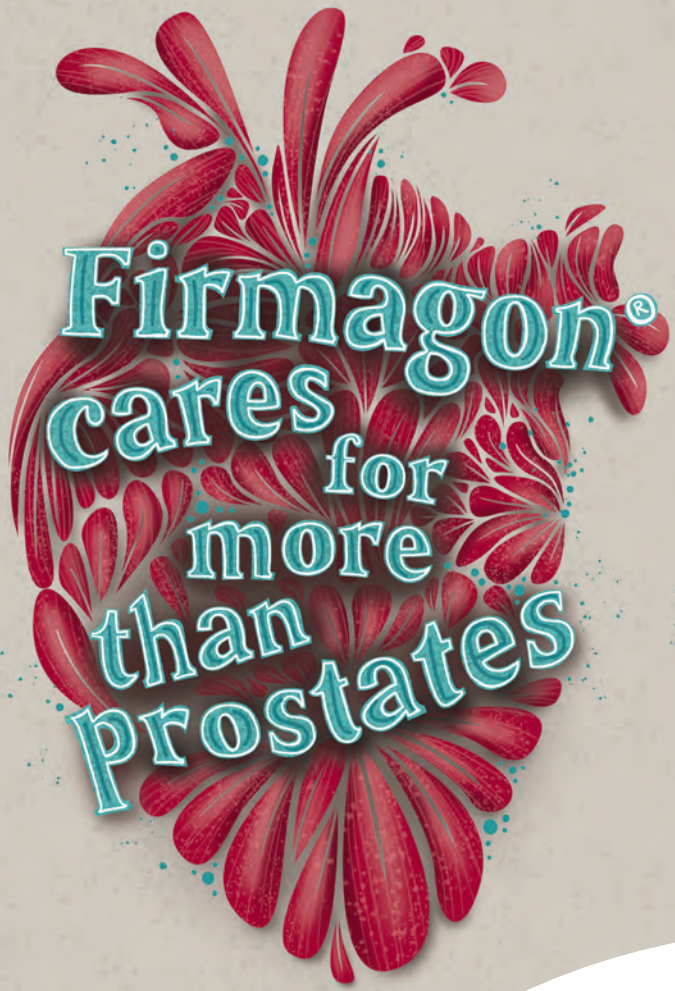
FIRMAGON® (degarelix) is a gonadotrophin releasing hormone (GnRH) antagonist indicated for the treatment of adult male patients with advanced hormone-dependent prostate cancer, also in combination with radiotherapy and as neo-adjuvant treatment prior to radiotherapy in patients with high-risk localised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



Discover an ADT that can help your high-risk CV patients[3-8]

FIRMAGON®
degarelix
Think beyond the prostate

For patients with prostate cancer, CVD is a major cause of death[9,10]

CVD is the leading cause of death in prostate cancer patients, after prostate cancer itself [9,10]

- As many as **30% of advanced prostate cancer patients** are likely to be at **high risk** of a CV event[9]
- **CVD-related healthcare costs** are estimated at **£7.4 billion** annually in England alone,[11] with one event costing an estimated average of **£3,449**[12,13]

The estimated CVD-related healthcare costs in Scotland, Wales and Northern Ireland are:

£800 million[14]

£550 million[14]

£412 million[14]

STAMP - Identification of patients with CVD[15]

EAU GUIDELINES: GnRH antagonists might be associated with less CV morbidity compared with agonists.[16]

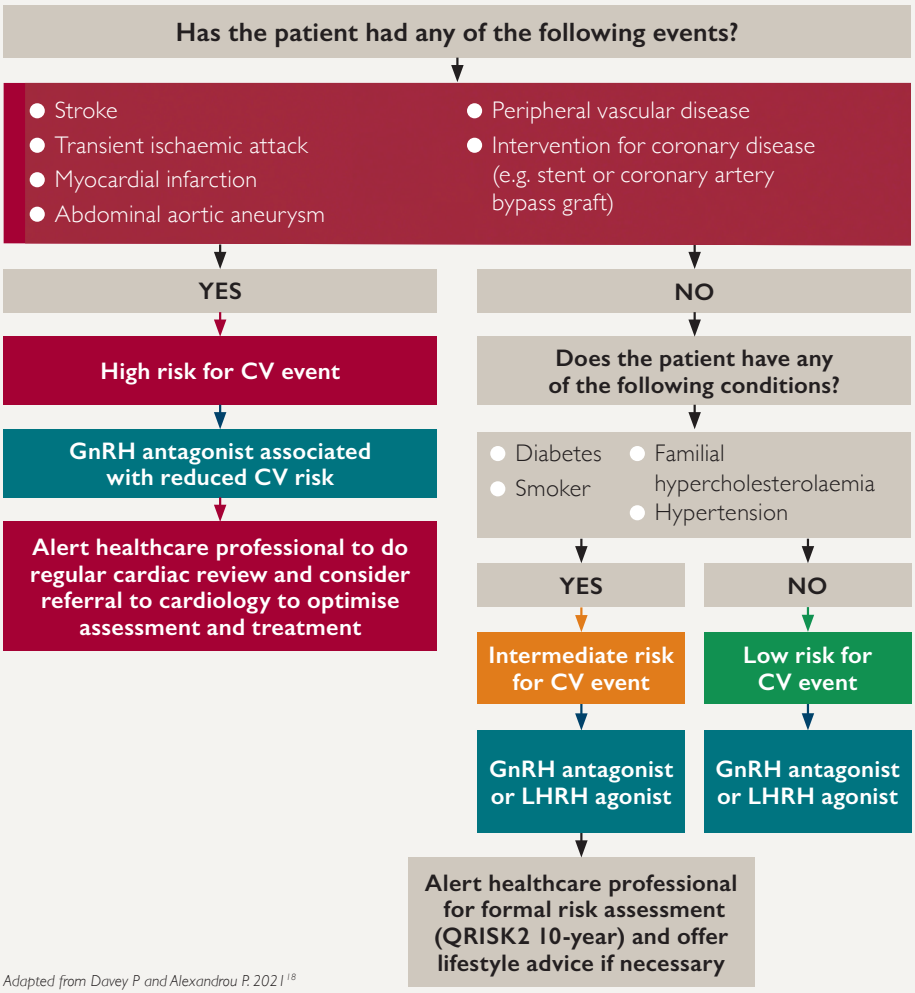
The STAMP tool can be used to help you identify patients with pre-existing CVD:

S	Stroke
T	Transient ischaemic attack
A	Abdominal aortic aneurysm or other aortic disease
M	Myocardial infarction, angina, or previous coronary revascularisation
P	Peripheral arterial disease

Adapted from Kenk M. et al 2020[15]

Identifying and managing patients with CVD[15,16]

A careful CV risk assessment should be considered in all prostate cancer patients receiving ADT.[17]



Adapted from Davey P and Alexandrou P. 2021[18]

FIRMAGON® significantly reduces the risk of CV events vs. LHRH agonists[3-8*]

Retrospective pooled analysis from six Phase III, prospective, RCTs of prostate cancer patients (n=2,328), initiated on FIRMAGON® or LHRH agonists.[3]

DURING THE FIRST YEAR OF TREATMENT:

Significantly lower risk of experiencing a CV event with FIRMAGON® patients vs. LHRH agonists in patients **with pre-existing CVD**

(HR: 0.44; 95% CI: 0.26–0.74; **p=0.002**)[3]

relative risk reduction[3]

absolute risk reduction[3]

With FIRMAGON®, the number needed to treat to prevent 1 CV event is 12[3]

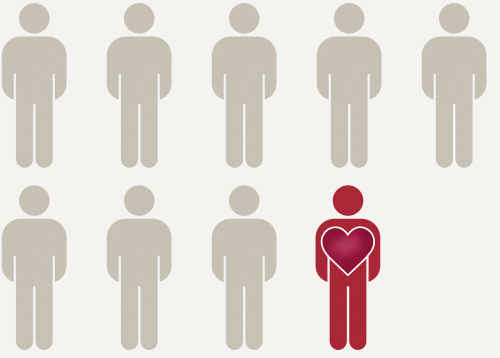
* LHRH agonists included goserelin and leuprorelin.

FIRMAGON® significantly lowers the risk of CV events vs. LHRH agonists in a UK real-world setting[4]

UK Primary Care database of patients with prostate cancer (population based cohort study)

(n=9,081, aged ≥40 years)[4]

- More patients prescribed FIRMAGON® had pre-existing CVD at baseline vs. patients on LHRH agonists[4*]
- **6.9%** estimated **relative risk of CV event** with FIRMAGON® vs. **17.7%** with LHRH agonists (**RR: 0.39**; 95% CI: 0.191-0.799; **p=0.01**)[4]



In a real-world setting, with FIRMAGON®, the number needed to treat to prevent 1 CV event was 9[4]**

* LHRH agonists refers to pooled data of patients receiving leuprorelin, goserelin and triptorelin.[4]
** Calculated by Ferring using relative and absolute risk reduction.[4]

FIRMAGON®: A different class of ADT that significantly reduces the risk of CV events vs. LHRH agonists[3-8]

CVD is the **leading cause of death** in prostate cancer patients, after prostate cancer itself[9,10]

CVD-related healthcare costs are a major burden to the NHS with just one event costing an estimated average of £3,449[12,13]

As a **GnRH antagonist**, FIRMAGON® blocks GnRH receptors for immediate and profound LH, FSH and testosterone suppression[19]

FIRMAGON® reduces the risk of CV events in patients with pre-existing CVD[3-8] and **improves overall survival** rates vs. LHRH agonists[20]

56% relative risk reduction and 8.2% absolute risk reduction of experiencing a CV event in patients with pre-existing CVD vs. LHRH agonists*
(HR: 0.44; 95% CI: 0.26–0.74; p=0.002)[3]

* Retrospective pooled analysis from six Phase III, prospective, RCTs of prostate cancer patients (n=2,328) initiated on FIRMAGON® or LHRH agonists. LHRH agonists included goserelin and leuprorelin.

For further resources scan the QR code or visit the website

www.ferringukhub.co.uk/urology/firmagon

SCAN ME

Date of preparation: March 2023
UK-FN-2200053

FERRING PHARMACEUTICALS

Abbreviations: ADT, androgen deprivation therapy; CI, confidence interval; CV, cardiovascular; CVD, cardiovascular disease; EAU, European Association of Urology; FSH, follicle-stimulating hormone; GnRH, gonadotrophin-releasing hormone; HR: hazard ratio; LH, luteinising hormone; LHRH, luteinising hormone-releasing hormone; OS, overall survival; PSA, prostate specific antigen; RR, risk ratio.

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: March 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: March 2023. **3.** Albertsen PC, *et al.* Eur Urol 2014;65:565–573. **4.** Davey P and Kirby MG. World J Urol 2021;39:307–315. **5.** Margel D, *et al.* J Urol 2019;202(6):1199–1208. **6.** Perrone V, *et al.* Ther Clin Risk Manag 2020;16:393–401. **7.** Cone EB, *et al.* J Clin Oncol 2020;38:6 Suppl 34. **8.** Zhang KW, *et al.* J Urol 2021;206: 613-622. **9.** Plummer C, *et al.* Trends Urol Men's Health 2017;13–18. **10.** Chowdhury S, *et al.* BJU Int 2013;112(2):182-9. **11.** Health Matters: Preventing cardiovascular disease. UK Health Security Agency. Available at: https://ukhsa.blog.gov.uk/2019/02/14/health-matters-preventing-cardiovascular-disease/. Last accessed: March 2023. **12.** Hospital Episode Statistics (HES) database. (Data for Jan-Dec 2021). **13.** Data on file, Ferring Pharmaceuticals Ltd. Based on HES data, Xiang-Ming *et al.*, 2017, NICE 2011. **14.** British Heart Foundation. Heart statistics 2022. Available at: https://www.bhf.org.uk/-/media/files/research/heart-statistics/cvdstatistics-2022-chapter-4-costs-final.xlsx?rev=58708e7a80054ab29717c2d4d868ad60&hash30328EBB41C05BF330223B54BA548AE8. Last accessed: March 2023. **15.** Kenk M, *et al.* Can Urol Assoc J 2020;14:E458–E464. **16.** Mottet N, *et al.* European Association of Urology. Prostate cancer guidelines. Available at: uroweb.org/guideline/prostate-cancer/. Last accessed: March 2023. **17.** Cereda V, *et al.* Heart Fail Rev 2022; 27(1):119-134. **18.** Davey P and Alexandrou K. Document number: UK-FN-2000065. August 2020. **19.** Drudge-Coates L. Int J Urol Nurs 2009;3(3):85–92. **20.** Klotz L, *et al.* Eur Urol 2014;66:1101–1108.

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-2200041

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