Prescribing Information: Fyremadel® (ganirelix acetate) 0.25 mg/0.5 ml solution for injection in pre-filled syringe.
Please consult the full Summary of Product Characteristics before prescribing.
Name: Fyremadel® 0.25 mg/0.5 ml solution for injection in pre-filled syringe. **Composition:** Each pre-filled syringe contains 0.25 mg of ganirelix (as acetate) in 0.5 ml aqueous solution. **Indication:** Prevention of premature luteinising hormone (LH) surges in women undergoing controlled ovarian hyperstimulation (COH) for assisted reproduction techniques (ART). **Dosage and administration:** COH with FSH or corifollitropin alfa may start at day 2 or 3 of menses. Fyremadel® (0.25 mg) should be injected subcutaneously once daily, starting on day 5 or 6 of FSH administration or on day 5 or 6 following the administration of corifollitropin alfa. The start day of Fyremadel® depends on ovarian response. Fyremadel® and FSH should be administered approximately at the same time. However, do not mix the preparations and use different injection sites. Continue daily treatment with Fyremadel® up to the day that sufficient follicles of adequate size are present. Final maturation of follicles can be induced by administering human chorionic gonadotrophin (hCG). Because of the half-life of Fyremadel®, the time between two Fyremadel® injections as well as the time between the last Fyremadel® injection and the hCG injection should not exceed 30 hours. **Method of administration**: Administer subcutaneously, preferably in the upper leg. Vary the injection site to prevent lipoatrophy. **Contraindications:** Hypersensitivity to the active substance or excipients, hypersensitivity to gonadotrophin-releasing hormone (GnRH) or any other GnRH analogue, moderate or severe renal or hepatic impairment. Pregnancy or breast feeding. **Special Warnings and Precautions:** Hypersensitivity reaction**:** Take special care in women with signs and symptoms of active allergic conditions. Hypersensitivity reactions (both generalised and local) have been reported with Fyremadel®, as early as with the first dose, including anaphylaxis (including anaphylactic shock) angioedema and urticaria. If a hypersensitivity reaction is suspected, discontinue Fyremadel® and treat appropriately. Fyremadel® treatment is not advised in women with severe allergic conditions. Latex allergy: The needle cover contains dry natural rubber/latex which comes into contact with the needle and may cause allergic reactions. Ovarian hyperstimulation syndrome (OHSS) may occur during or following ovarian stimulation and must be considered an intrinsic risk of gonadotrophin stimulation- treat symptomatically. Since infertile women undergoing assisted reproduction, and particularly in vitro fertilisation, often have tubal abnormalities the incidence of ectopic pregnancies might be increased. Early ultrasound confirmation that a pregnancy is intrauterine is therefore important. The incidence of congenital malformations after ART may be higher than after spontaneous conceptions. Clinical studies investigating more than 1000 new-borns found that the incidence of congenital malformations in children born after COH treatment using Fyremadel® was comparable with that reported after COH treatment using a GnRH agonist. The safety and efficacy of Fyremadel® have not been established in women weighing < 50 kg or > 90 kg. No drug interaction studies have been performed with Fyremadel®. **Pregnancy/breastfeeding:** Contraindicated. **Side effects:** Very common: local skin reaction at injection site (predominantly redness, with or without swelling). Uncommon: headache, malaise, nausea. Very rare: Hypersensitivity reactions (including anaphylaxis, anaphylactic shock, angioedema), worsening of pre-existing eczema**. Consult the summary of product characteristics in relation to other adverse reactions**. **Marketing Authorisation Number:** PL 31750/0055 **Marketing Authorisation Holder:** Sun Pharmaceutical Industries Europe B.V. Polarisavenue 87, 2132 JH Hoofddorp, The Netherlands. **Legal category:** POM **Basic NHS price:** Fyremadel® x 1 pre-filled syringe £19.35, Fyremadel® x 5 pre-filled syringes £96.75 **Date of preparation:** July 2023 Fyremadel® is a registered trademark. **PI Job Code:** UK-FYR-2300003.

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 Sun Pharmaceuticals Industries Europe B.V.
Tel : 0208 848 5052 Email : **medinfoeurope@sunpharma.com**