PUREGON SOLUTION®
Follitropin beta

Presentation: Puregon solution is available in vials or cartridges. Each vial contains 50, 100, 150 or 200IU follitropin beta in 0.5ml as an aqueous solution. Each cartridge contains 300, 600 or 900IU follitropin beta as an aqueous solution and must be used with the Puregon Pen. **Use**: ***In the female:*** Anovulation (including PCOD) in women unresponsive to clomiphene citrate. Controlled ovarian hyperstimulation to induce multiple follicles in medically assisted reproduction programs (e.g. IVF/ET, GIFT ICSI). ***In the male:*** Deficient spermatogenesis due to hypogonadotrophic hypogonadism. **Dosage and Administration:** Administered subcutaneously or intramuscularly (im vial presentations only). Refer to the cartridge SPC for details for switching between the pen-injector and a conventional syringe. Puregon® is more effective than urinary FSH in terms of a lower total dose and a shorter treatment period. Therefore, it is considered appropriate to give a lower dosage of Puregon® than generally used for urinary FSH. Adjust dosage depending on ovarian response monitored by oestrogens and/or ultrasound. ***Annovulation:*** In general, a sequential treatment scheme is recommended, starting with daily administration of 50IU. Ovulation may be induced by administration of hCG. ***Controlled Ovarian Hyperstimulation:*** A starting dose of 100-225 I.U. is recommended for at least the first four days, alone, or in combination with a GnRH agonist. Dose may then be adjusted individually, based upon ovarian response. Follicle maturation is achieved by administration of hCG. Oocyte recovery should be performed 34-35 hours after hCG administration. ***Deficient spermatogenesis:*** A dose of 450 IU each week, divided in 3 dosages of 150 IU concomitantly with hCG for at least 3-4 months. **Contraindications:** Ovarian, breast, uterine, testicular, hypothalamus and pituitary tumours; pregnancy; lactation; undiagnosed vaginal bleeding; hypersensitivity to any ingredients; primary ovarian failure; ovarian cysts or enlarged ovaries, not related to PCOD; malformations of the sexual organs; fibroid tumours of the uterus, primary testicular failure. **Precautions and warnings**: Other causes of infertility should be excluded. In pregnancies occurring after induction of ovulation with gonadotropins, there is an increased risk of multiple gestations. Council patients on the increased risk before treatment. Exclude uncontrolled non-gonadal endocrinopathies. There have been no reports of hypersensitivity to Puregon®, but there remains the possibility of anaphylactic responses. The first injection should only be performed under direct medical supervision. Since infertile women often have tubal abnormalities the incidence of ectopic pregnancies might be increased. Early ultrasound confirmation that a pregnancy is intrauterine is important. Rates of pregnancy loss in women undergoing ART are higher than in the normal population. Higher incidence of congenital malformation after ART compared to spontaneous conception. If unwanted ovarian hyperstimulation occurs administration of Puregon® should be discontinued. Pregnancy should be avoided and hCG must be withheld, because it may induce, in addition to multiple ovulation, ovarian hyperstimulation syndrome (OHSS). Reproductive neoplasms reported after multiple drug regimens in IVF treatment. In rare instances, venous or arterial-thromboembolism may occur in association with OHSS. Women with generally recognised risk factors for thrombosis may have an increased risk of venous or arterial thrombo-embolic events during or following treatment with gonadotrophins. In these women the benefits of IVF treatment needs to be weighed against the risks. May contain traces of streptomycin and/or neomycin, which may cause hypersensitivity reactions in susceptible people. Elevated endogenous FSH levels are indicative of primary testicular failure. Such patients are unresponsive to Puregon/hCG therapy. Semen analysis is recommended 4-6 months after start of treatment to assess response. **Pregnancy and Lactation**: Not indicated in pregnancy and lactation. **Interactions:** Concomitant use of Puregon and clomiphene citrate may enhance the follicular response. After pituitary desensitisation induced by a GnRH agonist, a higher dose of Puregon may be necessary to achieve an adequate follicular response. **Adverse Reactions** Bruising, pain, redness, swelling and itching at the injection site the majority of which are mild and transient in nature, very rarely erythema and rash. In women: unwanted ovarian hyperstimulation. Rarely thromboembolism has been associated with Puregon/hCG therapy as with other gonadotrophins. In men: occasionally gynaecomastia and acne as these are known effects of hCG. **Overdose:** The acute toxicity has been shown to be very low. Too high a dosage for more than one day may lead to ovarian hyperstimulation.
Marketing Authorisation Holder: NV Organon, Oss, The Netherlands
Marketing Authorisation Numbers:
Puregon 300 IU/0.36ml: EU/1/96/008/38 – 1 cartridge
Puregon 600 IU/0.72ml: EU/1/96/008/39 – 1 cartridge
Puregon 900 IU/1.08ml: EU/1/96/008/41 – 1 cartridge
Puregon 50IU: EU1/96/008/017 -1 vial
Puregon 100IU: EU1/96/008/023 - 1 vial
Puregon 150IU: EU1/96/008/026 - 1 vial
Puregon 200IU: EU1/96/008/029 - 1 vial

Ireland
Legal Category: Prescription Medicine

Basic NHS Cost:
Puregon 300 IU/0.36ml - 1 cartridge €159.30
Puregon 600 IU/0.72ml – 1 cartridge €318.60
Puregon 900 IU/1.08ml – 1 cartridge €477.90
Puregon 50IU- 1 vial €26.55
Puregon 100IU - 1 vial €53.10
Puregon 150IU - 1 vial €79.65
Puregon 200IU - 1 vial €106.20
Further information is available from Organon Laboratories Ireland c/o United Drug plc., Belgard Road, Tallaght, Dublin 24

UK
Legal Category: POM
Basic NHS Cost:
Puregon 300 IU/0.36ml - 1 cartridge £101.23
Puregon 600 IU/0.72ml - 1 cartridge £202.47
Puregon 900 IU/1.08ml – 1 cartridge £303.66
Puregon 50IU- 1 vial £18.74
Puregon 100IU - 1 vial £37.48
Puregon 150IU - 1 vial £50.62
Puregon 200IU - 1 vial £67.49
Further information is available from: Organon Laboratories Limited, Cambridge Science Park, Milton Road, Cambridge, CB4 0FL, UK Telephone: 01223 432700

March 2005