

## **OVUNAL SC**

**COMPOSITION :** Human Chorionic Gonadotropin (hCG) Purified (2000IU,5000IU,10000IU) **INDICATION:**In the female- Sterility due to the absence of follicle-ripening or ovulation.In combination with FSH or HMG, promotion of controlled superovulation in medically assisted reproduction programmes.In the male -Hypogonadotropic hypogonadism.Delayed puberty associated with insufficient gonadotrophic pituitary function. Sterility in selected cases of deficient spermatogenesis. **DOSAGE & ADMINISTRATION:** In the female -Sterility due to the absence of follicle-ripening or ovulation. 5,000–10,000 IU hCG to induce ovulation, following treatment with an FSH (Follicle Stimulating Hormone) or HMG (Human Menopausal Gonadotrophins) preparation.In combination with FSH or HMG, promotion of controlled superovulation in medically assisted reproduction programmes. 5,000–10,000 IU hCG 30 - 40 hours after the last FSH or HMG injection. Pregnyl should not be administered if the following criteria have not been met: at least 3 follicles greater than 17mm in diameter are present with  $17\beta$  estradiol levels of at least 3500 pmol/L (920 picogram/ml). Oocyte collection is carried out 32 - 36 hours after the hCG injection.As luteal phase support, two to three injections of 1,000 to 3,000 IU hCG each may be given within nine days of ovulation or embryo transfer, for example on day 3, 6 and 9 after ovulation induction or embryo transfer.In the male- Hypogonadotropic hypogonadism. 500–1,000 IU hCG 2-3 times weekly.Delayed puberty associated with insufficient gonadotrophic pituitary function. 1,500 IU hCG twice weekly for at least 6 months.Sterility in selected cases of deficient spermatogenesis. Usually, 3,000 IU hCG per week in combination with an FSH or HMG preparation.This treatment should be continued for at least three months before any improvement in spermatogenesis can be expected. During this treatment testosterone replacement therapy should be suspended. Once achieved, the improvement may sometimes be maintained by hCG alone. **METHOD OF ADMINISTRATION** After addition of the solvent to the freeze-dried substance, the solution should be given immediately by intramuscular or subcutaneous injection. Any unused solution should be discarded. Subcutaneous injection may be carried out by patient or partner, provided that proper instruction is given by the physician. Self administration of Pregnyl should only be performed by patients who are well-motivated, adequately trained and with access to expert advice.**CONTRAINDICATIONS:** Hypersensitivity to human gonadotrophins,Presence of uncontrolled non-gonadal endocrinopathies (e.g. thyroid, adrenal or pituitary disorders), Breast, uterine, ovarian tumours.,Abnormal (not menstrual) vaginal bleeding without a known/diagnosed cause.Known or suspected androgen-dependent tumours such as testicular tumours, carcinoma of the prostate or mammary carcinoma in males.Malformations of the reproductive organs incompatible with pregnancy.Fibroid tumours of the uterus incompatible with pregnancy.**WARNINGS & PRECAUTIONS:** In males and females: Hypersensitivity reactions:Hypersensitivity reactions, both generalised and local; anaphylaxis; and angioedema have been reported.General: should not be used for body weight reduction. HCG has no effect on fat metabolism, fat distribution or appetite. **INTERACTION:** No interaction studies have been performed; interactions with commonly used medicinal products can therefore not be excluded.**ADVERSE REACTIONS:**Immune system disorders -In rare cases generalized rash or fever may occur.General disorders and administrative site conditions- Local site reactions such as bruising, pain, redness, swelling and itching. Oedema. Occasionally allergic reactions have been reported, mostly manifesting as pain and/or rash at the injection site Tiredness.Nervous system disorders -Headache.Psychiatric disorders -Mood changes. Reproductive system and breast disorders-Unwanted ovarian hyperstimulation, mild or severe ovarian hyperstimulation syndrome **OVERDOSE:** The toxicity of human chorionic gonadotrophic hormone is very low. However, too high a dose may lead to hyperstimulation of the ovaries (For details, please refer full prescribing information)

(For the use of a registered medical practitioner or hospital or laboratory only)