HCG

Prescription Only

Human Chorionic Gonadotrophin

Composition

HCG consists of a freeze-dried powder for injection and a solvent for reconstitution. The active ingredient is Highly Purified (HP) Human Chorionic Gonadotrophin BP (HCG) which is obtained from the urine of pregnant women, has luteinizing hormone (LH) activity.

- HCG 10000 IU: Each vial contains 10000 IU Highly Purified (HP) Human Chorionic Gonadotrophin BP.
- HCG 5000 IU: Each vial contains 5000 IU Highly Purified (HP) Human Chorionic Gonadotrophin BP.

Pharmacological Action

Pharmacodynamic Properties

HCG contains Highly Purified Human Chorionic Gonadotrophin which has LH activity. LH is indispensable in normal female and male gamete growth and maturation, and gonadal steroid production.

In the female:

HCG is given as a substitute for the endogenous mid-cycle LH surge to induce the final phase of follicular maturation, leading to ovulation. **HCG** is also given as a substitute for endogenous LH during the luteal phase.

In the male:

HCG is given to stimulate Leydig cells to promote the production of testosterone.

Pharmacokinetic Properties

Maximal **HCG** plasma levels will be reached approximately six hours after a single injection of **HCG**. **HCG** is for approximately 80 percent metabolized, predominantly in the kidneys. Following intramuscular injection (IM) the apparent elimination half-life of **HCG** is about 2 days. On basis of the recommended dose regimens and elimination half-life, accumulation does not occur.

Indications

In the female:

- Ovulation induction in infertility due to anovulation or impaired follicle-ripening.
- Preparation of follicles for puncture in controlled ovarian hyperstimulation programs (ART).
- Luteal phase support.
- Threatened and habitual abortion.

In the male:

- Hypogonadotropic hypogonadism (also cases of idiopathic dysspermias have shown a positive response to gonadotropins).
- Used to treat oligospermia.
- Delayed puberty associated with insufficient gonadotropic pituitary function.

Dosage & Administration

HCG is given by IM/SC use only. The injection should be reconstituted with 0.9% NaCl Injection provided, immediately prior to use.

In the female:

Anovulatory infertility: **HCG** Inj. 5000 IU to 10000 IU is administered in mid-cycle, following treatment with Menotrophin Inj. according to a recognised scheme. Details of Menotrophin Inj. dosage and monitoring are available on request.

Luteal phase support: Two repeat injections of 2500 IU to 5000 IU. Each may be given within nine days following ovulation or embryo transfer (for example on day 3, 6 and 9 after ovulation induction).

In the male:

Oligospermia: 2500 IU to 5000 IU **HCG**, two times per week. During this treatment testosterone replacement therapy should be suspended.

Hypogonadotropic hypogonadism: 2500 IU to 5000 IU **HCG**, two times per week. If the main complaint is sterility, additional doses of an FSH-containing (75 IU FSH or 75 IU HMG) are to be administered daily or two to three times a week. 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 in some cases be maintained by **HCG** alone.

Contraindications

Known or suspected androgen-dependent tumours, such as prostatic carcinoma or breast carcinoma in the male.

Warnings and Precautions

- In pregnancies occurring after induction of ovulation with gonadotropic preparations, there is an increased risk of multiplets birth.
- Unwanted ovarian hyperstimulation: In patients treated for infertility due to anovulation or impaired follicular ripening, the prior administration of an FSH containing preparation may lead to unwanted ovarian hyperstimulation. Therefore ultrasonic assessment of follicular development and determinations nations of estrogen levels should be performed prior to FSH-treatment and at regular intervals during FSH-treatment. Estrogen levels may rise very rapidly, e.g. more than a daily doubling for two or three consecutive days, and possibly reach excessively high values. If this unwanted ovarian hyperstimulation occurs (i.e. not as part of a treatment preparing for IVF/ET or GIFT/ZIFT), the administration of the FSH-containing preparation should be discontinued immediately. In that case Human Chorionic Gonadotrophin must not be given, because the administration of an LH-active gonadotrophin at this stage may induce, in addition to multiple ovulations, the ovarian hyperstimulation syndrome. This warning is particularly important with respect to patients with polycystic ovarian disease. Clinical symptoms of mild ovarian hyperstimulation syndrome are gastro-intestinal problems (pain, nausea, diarrhoea), painful breasts, and mild to moderate enlargement of ovaries and ovarian cysts. In rare cases severe ovarian hyperstimulation syndrome occurs, which may be life-threatening. This is characterized by large ovarian cysts (prone to rupture), ascites, often hydrothorax and occasionally thromboembolic phenomena.

Adverse Reactions

Allergic reactions have occasionally been reported with the use of urinary gonadotrophin preparations. These mostly involve local reactions such as pain and rash at the injection site, and generalized reactions such as rash and fever.

In the female:

Unwanted ovarian hyperstimulation syndrome which is a characteristic symptoms of unwanted ovarian hyperstimulation and the ovarian hyperstimulation syndrome are included under 'Special warnings and special precautions for use.

In the Male:

Water and sodium retention is occasionally seen after administration of high dosages; this is regarded as a result of excessive androgen production.

Treatment with Human Chorionic Gonadotrophin leads to increased androgen production.

Therefore:

- Patients with latent or overt cardiac failure, renal dysfunction, hypertension, epilepsy or migraine (or a history of these conditions) should be kept under close medical supervision, since aggravation or recurrence may occasionally be induced as a result of increased androgen production.
- Human Chorionic Gonadotrophin should be used cautiously in prepubertal boys to avoid premature epiphyseal closure or precocious sexual development. Skeletal maturation should be monitored regularly.

Interactions

No interactions of clinical relevance are known.

Pregnancy and Lactation

Human chorionic gonadotrophin may be used for luteal phase support in pregnancy.

Overdosage

The acute toxicity of urinary gonadotropin preparations has been shown to be very low. There are no symptoms of an acute parenteral overdose known in humans.

Special Precautions for Storage

- Store at 2°C to 8°C (in a refrigerator).
- Do not keep in deep freeze.

Commercial Packs

- HCG 10000 IU: Each pack contains 1 vial of 10000 IU Highly Purified (HP) Human Chorionic Gonadotrophin as Lyophilized powder with 0.9% NaCl Injection in 1 ml ampoule & Sterile Disposable Syringe.
- HCG 5000 IU: Each pack contains 1 vial of 5000 IU Highly Purified (HP) Human Chorionic Gonadotrophin as Lyophilized powder with 0.9% NaCl Injection in 1 ml ampoule & Sterile Disposable Syringe.

Manufactured by :

POPULAR

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