Ovugen™

Chorionic Gonadotrophin BP for Injection

DESCRIPTION

Ovugen™ is the active ingredient of highly purified human chorionic gonadotrophin (hCG). Human chorionic gonadotrophin is a polypeptide hormone produced by the human placenta and composed of an alpha and a beta sub-unit. The alpha sub-unit is essentially identical to the alpha sub-units of the human pituitary gonadotrophins, luteinizing hormone (LH) and follicle-stimulating hormone (FSH), as well as to the alpha sub-unit of human thyroid-stimulating hormone (TSH). The beta sub-units of these hormones differ in amino acid sequence. Chorionic gonadotrophin is obtained from the urine of pregnant women. It is standardized by a biological assay procedure.

The action of human chorionic gonadotrophin (hCG) is virtually identical to that of pituitary LH, although hCG appears to have a small degree of FSH activity as well. It stimulates production of gonadal steroid hormones by stimulating the interstitial cells (Leydig cells) of the testis to produce androgens and the corpus luteum of the ovary to produce progesterone.

During the normal menstrual cycle, LH participates with FSH in the development and maturation of the normal ovarian follicle, and the mid-cycle LH surge triggers ovulation. hCG can substitute for LH in this function. During a normal pregnancy, hCG secreted by the placenta maintains the corpus luteum after LH secretion decreases, supporting continued secretion of estrogen and progesterone and preventing menstruation.

Androgen stimulation in the male leads to the development of secondary sex characteristics and may stimulate testicular descent when no anatomical impediment to descent is present. This descent is usually reversible when hCG is discontinued.

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 dyspermia have shown a positive response to gonadotrophins).
- Delayed puberty associated with insufficient gonadotropic pituitary function. Cryptorchidism, (not due to anatomical obstruction).
- Used to treat oligospermia.

DOSAGE AND ADMINISTRATION

INTRAMUSCULAR / SUBCUTANEOUS USE ONLY.

The injection should be reconstituted with 0.9% sodium chloride injection, immediately prior to use.

In the female:

Anovulatory infertility: Ovugen™ Inj. 5000 IU to 10000 IU is administered in mid-cycle, following treatment with Menotrophin Inj. according to a recognized scheme.

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 **Ovugen™**, two times per week. During this treatment testosterone replacement therapy should be suspended.

Hypogonadotropic hypogonadism: 2500 IU to 5000 IU **Ovugen™**, 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 **Ovugen™** alone.

CONTRAINDICATIONS

- Prior hypersensitivity reactions to human gonadotrophins, including hCG.
- High serum FSH, indicating primary gonadal failure in women.
- Presence of uncontrolled non-gonadal endocrinopathies (e.g., thyroid, adrenal, or pituitary disorders).
- Tumors of the hypothalamus or pituitary gland and ovary, breast, or uterus in females and breast or prostate in males.
- Malformations of the reproductive organs incompatible with pregnancy.
- Fibroid tumors of the uterus incompatible with pregnancy.
- Abnormal vaginal bleeding of undetermined origin.

SIDE EFFECTS

Allergic reactions have occasionally been reported with the use of urinary gonadotrophin preparations. Headache, irritability, restlessness, depression, fatigue, edema, precocious puberty, gynecomastia, pain at the site of injection. Hypersensitivity reactions both localized and systemic in nature, including erythema, urticaria, rash, angioedema, dyspnea and shortness of breath, have been reported.

PRECAUTIONS AND WARNINGS

Human chorionic gonadotrophin should be used in conjunction with human menopausal gonadotrophins only by physicians experienced with infertility problems who are familiar with the criteria for patient selection, contraindications, warnings, precautions, and adverse reactions described in the package insert for menotropins.

- Ovarian Hyperstimulation Syndrome (OHSS)- Ovarian hyperstimulation, a syndrome of sudden ovarian enlargement, ascites with or without pain, and/or pleural effusion. If there is evidence that OHSS may be developing prior to hCG administration, withhold hCG.
- Enlargement of preexisting ovarian cysts or rupture of ovarian cysts with resultant hemoperitoneum. Adherence to the recommended hCG dose and treatment regimen and careful monitoring of ovarian response is important to reduce the risk.
- Arterial thromboembolism. In women with recognized risk factors, the benefits of ovulation induction, in vitro fertilization (IVF) or intracytoplasmic sperm injection (ICSI) treatment need to be weighed against the risks.
- Multi-fetal gestation and births have been reported with all gonadotrophin therapy including hCG. Advise women of the potential risk of multiple births before starting treatment with gonadotrophins including hCG.
- Anaphylaxis and other hypersensitivity reactions have been reported with urinary-derived hCG products.
- Induction of androgen secretion by hCG may cause fluid retention. Use hCG with caution in patients with cardiac or renal disease, hypertension, epilepsy, migraine, or asthma.
- hCG may cause sexual precocity when administered in young patients (males) for cryptorchidism. If signs are observed, treatment should be stopped. If continued therapy is considered necessary, a reduced dosage regimen should be instituted.
- Induction of androgen secretion by hCG may induce precocious puberty in patients treated for cryptorchidism. Therapy should be discontinued if signs of precocious puberty occur.

USE IN PREGNANCY AND LACTATION

Human chorionic gonadotrophin may be used for luteal phase support in pregnancy but is discontinued upon confirmation of pregnancy. There are no data on the use of hCG in pregnancy.

It is not known whether chorionic gonadotrophin is excreted in human milk. Caution should be exercised when chorionic gonadotrophin is administered to a nursing woman. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for hCG and any potential adverse effects on the breastfed child from hCG or from the underlying maternal condition.

DRUG INTERACTION

No clinically significant drug interactions have been reported during u-hCG therapy.

OVERDOSE

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

STORAGE

Ovugen™ should be stored in a refrigerator (2 °C to 8 °C temperature). Do not freeze. Keep away from light and wet place. Keep out of reach of children.

PACKAGING

Ovugen™ 5000 for injection:

Each box contains 1 vial of Chorionic Gonadotrophin BP 5000 IU for injection, 1 mL 0.9% NaCl injection in ampoule, 2 mL disposable syringe, alcohol pad, first aid band and ampoule breaker included as accessories.

Ovugen™ 10000 for injection:

Each box contains 1 vial of Chorionic Gonadotrophin BP 10000 IU for injection, 1 mL 0.9% NaCl injection in ampoule, 2 mL disposable syringe, alcohol pad, first aid band and ampoule breaker included as accessories.

SK+F
Manufactured by
ESKAYEF PHARMACEUTICALS LTD.
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R/PM2701 V01