SIDE EFFECTS:
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.
In the female:- Reproductive system and breast disorders: Unwanted ovarian hyperstimulation, mild or severe ovarian hyperstimulation syndrome (OHSS): Mild OHSS: painful breasts, mild to moderate enlargement of ovaries, ovarian cysts, Abdominal pain, Abdominal discomfort, Gastrointestinal symptoms such as nausea, diarrhoea and bloating Severe OHSS: Large ovarian cysts (prone to rupture), Acute abdominal pain, Ascites, Weight gain, Hydrothorax In rare instances, thromboembolism has been associated with FSH/hCG therapy. Not all symptoms described are always associated to OHSS.
In the male:- Metabolism and nutrition disorders: Water and sodium retention is occasionally seen after administration of high dosages; this is regarded as a result of excessive androgen production. Reproduction system and breast disorders: HCG treatment may sporadically cause gynaecomastia. Skin and subcutaneous tissue disorders: Acne may occur occasionally during hCG therapy.

Symptoms and Treatment of Overdose:
The acute toxicity of urinary gonadotropin preparations has been shown to be very low. Nevertheless, there is a possibility that too high a dosage of hCG may lead to ovarian hyperstimulation syndrome.

STORAGE CONDITION:
Vials of **HuCoG** with 1ml Sodium Chloride Injection BP as solvent should be stored between 2°C-8°C. Do not freeze. Protect from light.
Reconstituted solution of **HuCoG** should be used immediately after preparation. Discard any unused portion.

SHELF LIFE:
HuCoG: 36 months.
Solvent Sodium Chloride: 60 months.

PRESENTATION:
HuCoG is supplied in vials containing sterile, powder for injection having activity of 5000 IU. Each vial is accompanied by an ampoule with the protective sleeve containing 1 ml of sodium chloride Injection B.P. as diluent in a carton along with pack insert and an ampoule breaking manual.

REVISION DATE:
APRIL 2024

Product Registration Holder :
BSV BioScience Malaysia Sdn. Bhd
No.3, JLN 19/1, 46300, P.J, Selangor, Malaysia.

Manufactured by :
BSV BHARAT SERUMS AND VACCINES LIMITED
Plot No. K-27, K-27 Part and K-27/1, Anand Nagar, Jambivili Village, Additional MIDC, Ambernath (East), Thane 421506, Maharashtra State, India.

IN90051E2MY

For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory.

Chorionic Gonadotrophin Injection B.P.

HuCoG 5000 I.U.

Freeze Dried

For Subcutaneous / Intramuscular Injection only

COMPOSITION :
Each vial contains :
Chorionic Gonadotrophin B.P. ..... 5000 I.U.

One I.U. of Chorionic Gonadotrophin is defined as the activity contained in 1.279 mg of the 2nd International Standard Preparation.

Excipients :
Mannitol B.P., Sucrose B.P., Sodium Ascorbate B.P., Anhydrous Di-sodium Hydrogen Phosphate B.P. and Phosphoric Acid B.P.

Each vial of **HuCoG** contains: Chorionic Gonadotrophin and each vial is accompanied by an ampoule of Sodium Chloride Injection B.P. 1ml.

PRODUCT DESCRIPTION :
Before Reconstitution
A white or almost white amorphous powder of cake.
After Reconstitution
A clear colourless liquid.
Solvent Sodium Chloride Injection
A clear colourless solution.

Pharmacodynamics :
HCG is a preparation of human chorionic gonadotrophin obtained from the urine of pregnant women. It stimulates the steroid genesis in the gonads by virtue of a biological effect similar to that of LH (Luteinizing hormone, which is the same as interstitial cell stimulating hormone). In the male it promotes the production of testosterone and in the female the production of estrogens and particularly of progesterone after ovulation. In certain cases, this preparation is used in combination with human menopausal gonadotrophin (HMG).

ATC Code: G03GA01 - Chorionic Gonadotropin.

Pharmacokinetics :
(HCG) is administered by intramuscular injection. The maximum serum level of **(HCG)** is reached after 4 to 12 hours (dose-dependent) and decreases afterwards with a half-life of 29 to 36 hours. Due to the slow elimination, **(HCG)** may cumulate in serum after several (e.g. daily) intramuscular injections. **(HCG)** is metabolized renally whereby about 10 - 20% can be found in its original form in urine, while the main amount is probably excreted as the beta-core fragment.

New Size : L x H = 215 x 135 mm

Pantone Process Black C
50% Pantone Process Black C
40% Pantone Process Black C
20% Pantone Process Black C

Paper : 40 gsm, ITC Print Paper
1 Vertical & 2 Horizontal Folds

Outline & Cutting marks not to print
Back to Back Printing

Artwork Code No. : IN90051E2MY

INDICATIONS:
In the female: Ovulation induction in subfertility due to anovulation or impaired follicle-ripening. Preparation of follicles for puncture in controlled ovarian hyperstimulation programs (for medically assisted reproductive techniques). Luteal phase support. In the male: Hypogonadotropic hypogonadism (also cases of idiopathic dysspermias have shown a positive response to gonadotropins). Delayed puberty associated with insufficient gonadotropic pituitary function. Cryptorchidism, not due to anatomical obstruction.

RECOMMENDED DOSE:
Dosage in the female: Ovulation induction in subfertility due to anovulation or impaired follicle-ripening Usually, one injection of 5000-10000 I.U. **HuCoG** to complete treatment with an FSH-containing preparation. Preparation of follicles for puncture in controlled ovarian hyperstimulation programs Usually, one injection of 5000-10000 I.U. **HuCoG** to complete treatment with an FSH-containing preparation. Luteal phase support Two to three repeat injections of 1000 to 3000 I.U. may be given within 9 days following ovulation or embryo transfer (for example on day 3, 6 and 9 after ovulation induction)

Dosage in the male: Hypogonadotropic hypogonadism 1000-2000 I.U. **HuCoG** two to three times per week. If the main complaint is subfertility, Pregnyl may be given with an additional follitropin (FSH)-containing preparation 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 sometimes be maintained by **(HCG)** alone. Delayed puberty associated with insufficient gonadotropic pituitary function 1500 I.U. two to three times weekly for at least six months Cryptorchidism, not due to anatomical obstruction - Under 2 years of age: 250 I.U. twice weekly for six weeks - Under 6 years of age: 500-1000 I.U. twice weekly for six weeks - Over 6 years of age: 1500 I.U. twice weekly for six weeks. If necessary, this treatment can be repeated.

Reconstitution Instruction:
Reconstitute the contents of vial containing **HuCoG** in 1ml of Sodium Chloride Injection BP and administer subcutaneous/ intramuscular immediately.

Route of Administration:
Intramuscular (IM) + Subcutaneous (SC)

CONTRAINDICATIONS:
Hypersensitivity to human gonadotropins or any of the excipients. Known or suspected sex hormone-dependent tumours, such as ovary, breast and uterine carcinoma in female and prostatic or breast carcinoma in the male. Malformations of the sexual organs incompatible with pregnancy. Fibroid tumours of the uterus incompatible with pregnancy.

WARNINGS AND PRECAUTIONS:
hCG should be given with care to patients in whom fluid retention might be a hazard, as in asthma, epilepsy, migraine or cardiac or renal disorders. hCG preparations should only be used under the supervision of a specialist having available adequate facilities for appropriate laboratory monitoring.

In the female:
Use in induction of ovulation may result in ovarian enlargement or cysts, acute abdominal pain, superovulation or multiple pregnancies, particularly if endocrine monitoring is inadequate. Since infertile women undergoing assisted reproduction, and particularly IVF, often have tubal abnormalities the incidence of ectopic pregnancies might be increased. Early ultrasound confirmation that a pregnancy is intrauterine is therefore important. Rates of pregnancy loss in women undergoing assisted reproductive technologies (ART) are higher than in the normal population. Prior to treating patients for inadequate endogenous stimulation of the gonads, an examination should be performed to exclude anatomical abnormalities of the genital organs or nongonadal endocrinopathies (e.g., thyroid or adrenal disorders, diabetes). Primary ovarian failure should be excluded by the determination of gonadotrophin levels. Unwanted hyperstimulation During treatment of female patients, determinations of oestrogen levels and assessment of ovarian size and if possible, ultrasonography should be performed prior to treatment and at regular intervals during treatment. High dosages may cause oestrogen levels to rise excessively rapidly, e.g., more than doubling on 2 or 3consecutive days, and possibly reaching excessively high pre-ovulatory values. The diagnosis of unwanted ovarian hyper stimulation may be confirmed by ultrasound examination. If unwanted hyperstimulation occurs (i.e., not as part of a treatment preparing for IVF/ET or GIFT or other assisted reproduction techniques), the administration of HMG should be discontinued immediately. hCG must not be given, because the administration of an hLH 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. The severe form of ovarian hyperstimulation syndrome may be life-threatening and is characterized by large ovarian cysts (prone to rupture), acute abdominal pain, ascites, very often hydrothorax and occasionally thrombo-embolic pnenomena.

- Women with generally recognised risk factors for thrombosis, such as a personal or family history, severe obesity (Body Mass Index> 30 kg/m2) or thrombophilia, may have an increased risk of venous or arterial thromboembolic events, during or following treatment with gonadotrophins. In these women the benefits of IVF treatment need to be weighed against the risks. It should be noted, however, that pregnancy itself also carries an increased risk of thrombosis. -There have been reports of ovarian and other reproductive system neoplasms, both benign and malignant, in women who have undergone multiple drug regimens for infertility treatment. It is not yet established whether or not treatment with gonadotrophins increases the baseline risk of these tumours in infertile women. **HuCoG** should not be used for body weight reduction. HCG has no effect on fat metabolism, fat distribution or appetite.

In the male:
Treatment with hCG 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. hCG should be used cautiously in prepubertal boys to avoid premature epiphyseal closure or precocious sexual development. Skeletal maturation should be monitored regularly.

INTERACTIONS WITH OTHER MEDICATIONS:
Interactions of **HuCoG** with other medicines have not been investigated; interactions with commonly used medicinal products can therefore not be excluded. Following administration,

HuCoG may interfere for up to ten days with the immunological determination of serum/urinary hCG, leading to a false positive pregnancy test.

PREGNANCY AND LACTATION:
HuCoG may be used for luteal phase support only but must not be used afterwards during pregnancy. It must not be used during lactation.

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