Side Effects :
Headache, irritability, restlessness, depression, fatigue, edema, gynecomastia, sexual precocity, pain at the site of injection.

Adverse Events :
The adverse reactions for use in **infertility** are: (1) Ovarian hyperstimulation **(OHSS)**, a syndrome of sudden ovarian enlargement, ascites with or without pain, and/or pleural effusion, (2) Rupture of ovarian cysts with resultant hemoperitoneum, (3) Multiple births, and (4) Arterial thrombo-embolism.

PRECAUTION :
HCG should be used in conjunction with human menopausal gonadotropins 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.

Interaction with other medicinal products and other forms of interaction :
Concomitant use of **HuCoG Injection** with other agents used to stimulate ovulation (e.g. HMG, clomiphene citrate) may potentiate the follicular response. (See Warnings Precaution & Overdosage.)

Overdose :
The effects of an overdose of **HuCoG Injection** are unknown, nevertheless one could expect ovarian hyperstimulation syndrome **(OHSS)** to occur, which is further described as below:

Ovarian Hyperstimulation Syndrome (OHSS) : *(See Warnings) :*
OHSS is a medical event distinct from uncomplicated ovarian enlargement. OHSS is a syndrome that can manifest itself with increasing degrees of severity. It comprises marked ovarian enlargement, high serum sex steroids, and an increase in vascular permeability which can result in an accumulation of fluid in the peritoneal, pleural and, rarely, in the pericardial cavities.
The following symptomatology may be observed in severe cases of OHSS : abdominal pain, abdominal distension, severe ovarian enlargement, weight gain, dyspnoea, oliguria and gastrointestinal symptoms including nausea, vomiting and diarrhoea.

Adherence to recommended HuCoG Injection dosage, regimen of administration and careful monitoring of therapy will minimize the incidence of ovarian hyper stimulation and multiple gestations. In ART, aspiration of all follicles prior to ovulation may reduce the occurrence of hyper stimulation. OHSS may be more severe and more protracted if pregnancy occurs. Most often, OHSS occurs after hormonal treatment has been discontinued and reaches its maximum at about seven to ten days following treatment. Usually, OHSS resolves spontaneously with the onset of menses. If severe OHSS occurs, gonadotrophin treatment should be stopped if still ongoing, the patient hospitalized and specific therapy for OHSS started. This syndrome occurs with higher incidence in patients with polycystic ovarian disease.

Ovarian response should be carefully monitored to minimize the risk of overstimulation. If the ovaries are abnormally enlarged on last day of gonadotrophin therapy, HCG should not to be administered in this course therapy. This reduces development of OHSS (Ovarian Hyperstimulation Syndrome). Use of ultrasound monitoring of ovarian response and/or measurement of serum estradiol levels can further minimize the risk of overstimulation.

Storage :
Vials of ***HUCOG HP*** should be stored between 2°C - 8°C. Do not freeze. Protect from light. Any unused portion should be discarded.

Presentation :
HUCOG HP is supplied in vials containing sterile having activity of 2000 I.U. / 5000 I.U. / 10000 I.U.

To report Suspected Adverse Reactions, contact Bharat Serums and Vaccines at pv@bharatserums.com or visit the website www.bharatserums.com/adverse.html

Manufactured in India by :
BHARAT SERUMS AND VACCINES LIMITED
Plot No. K-27, Additional M.I.D.C. Ambernath (E) - 421 501

IN90226D2

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

Highly Purified Chorionic Gonadotrophin Injection

हुकॉग
HUCOG®

२००० एचपी / ५००० एचपी / १०००० एचपी
2000 HP / 5000 HP / 10000 HP HP

For Subcutaneous / Intramuscular Injection only

Composition :
Each ml contains :
Chorionic Gonadotrophin highly purified I.H. ..... 2000 I.U. / 5000 I.U. / 10000 I.U.
Water for Injection I.P. ..... q.s.
Excipients & Stabilizers :
Disodium Hydrogen Phosphate Dihydrate B.P., Benzyl Alcohol I.P., Sucrose I.P., Poloxamer 188 U.S.P./NF, Methionine B.P., Phosphoric acid I.P.

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

Properties :
Chorionic Gonadotrophin (HCG) is a hormonal substance obtained from urine of pregnant women. Its action is predominantly luteinizing.

Indications :
Anovulatory infertility :
In the female, ***HUCOG HP*** is used in the treatment of anovulatory infertility. where its administration would form part of recognized treatment regimen involving prior stimulation of follicular maturation and endometrial proliferation e.q. with Menotropin Injection ***(HUMOG HP)***.

Hypogonadotrophin hypogonadism and cryptorchidism :
In the male, ***HUCOG HP*** stimulates the interstitial cells of the testes and consequently the secretion of androgens and the development of secondary sexual characteristics. With concomitant Menotropin Injection therapy, ***HUCOG HP*** stimulates the induction and maintenance of spermatogenesis.

Dosage and Administration :
HUCOG HP is given by subcutaneous / intramuscular injection only.

Anovulatory infertility :
HUCOG HP 10000 I.U. is administered in mid-cycle, following treatment with Menotropin Inj. ***(HUMOG HP)*** according to a recognised scheme. Details of Menotropin Inj. ***(HUMOG HP)*** dosage and monitoring are available on request.

Hypogonadotrophic hypogonadism :
HUCOG HP 2000 I.U. twice weekly concomitant with Menotropin Inj. ***(HUMOG HP)*** (1 vial three times a week) if necessary for a minimum period of four months.

Cryptorchidism :
Equivalent to 1000 I.U. of ***HUCOG HP*** on alternate days for several weeks.

Contra-Indication and Warnings :
Stimulation of ovulation with ***HUCOG HP*** may lead to superovulation and the hyperstimulation syndrome. Oestrogen assays will detect the excessive response so that ***HUCOG HP*** **(HCG)** may be withheld in that particular treatment cycle. In the male, high dosages of ***HUCOG HP*** may lead to oedema and in such cases dosages should be considerably reduced.

If signs of sexual precocity are observed a reduced dosage regimen should be instituted.