

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

MENOTROPINS FOR INJECTION U.S.P.

(Human Menopausal Gonadotropin Injection)

HuMoG[®]

(For Intramuscular Injection only)



COMPOSITION:

Each vial contains:

Menotropins U.S.P. equivalent to activity of

Follicle stimulating hormone.....75/150 I.U.

Luteinizing hormone75/150 I.U.

Added substance: Mannitol I. P.

One I.U. of human urinary FSH and one I.U. of human urinary LH are defined as the activities contained in 0.11388 mg and 0.13369 mg of the 1st international Standard respectively.

PROPERTIES:

HuMoG[®] (Human Menopausal Gonadotropin) is a hormonal substance containing FSH and LH in a ratio 1:1 in the female, **HuMoG[®]** stimulates both the growth and the maturation of follicles, it induces an increase in the oestrogen levels and a proliferation of the endometrium. In the male, **HuMoG[®]** stimulates the spermatogenesis

by acting on the production of the androgen-binding protein in the seminiferous tubules of the Sertoli cells.

INDICATIONS:

Women:

HuMoG[®] and subsequently **HuCoG**[®] (Human Chorionic Gonadotropin) are indicated for the induction of ovulation in the amenorrhoeic patient or anovulatory women with regular or irregular cycles.

Men:

HuMoG[®] with concomitant **HuCoG**[®] therapy is indicated for the stimulation of spermatogenesis in men who have primary or secondary Hypogonadotropic hypogonadism.

DOSAGE AND ADMINISTRATION:

HuMoG[®] is given by intramuscular injection. The powder for injection should be reconstituted with the Sodium Chloride injection provided immediately prior to use.

Upto 5 vials of **HuMoG**[®] may be dissolved in 1 ml of Sodium Chloride injection. Discard any unused portion.

Women:

The object is to develop a single matured Graffian follicle with individually tailored doses of **HuMoG**[®] over several days and to give **HuCoG**[®] to release the ovum.

Follicular development is judged by the concentration of oestrogen, measured in blood or urine. Clinical assessment of the response including pelvic examination and cervical mucus studies should also be performed. **HuMoG**[®] administration should continue until an adequate oestrogen level is achieved.

If the oestrogen values are less than either 180 nmol/24 hr. (50ug/24 hr) for tested urinary oestrogen or 1100pmol/L (300pg/ml) for plasma 17B-Oestradiol follicular development may be inadequate. Conversely, if the levels are higher than either 514 nmol/24 hr (140ug/24hr) for total urinary oestrogens or 3000pmol/L (800pg/ml) for plasma 17B -Oestradiol, there is an increased risk of ovarian hyperstimulation and **HuCoG**[®] should be withheld. The optimal time for **HuCoG**[®] administration is the day of the urinary oestrogen peak or the day after the plasma 17B -oestradiol peak. In the anovulatory patient the stimulated follicles will not liberate ova spontaneously. Follicular rupture had to be achieved by injecting **HuCoG**[®] which stimulates the normal surge of LH at ovulation.

TWO DOSAGE SCHEDULES BE EMPLOYED:

Schedule 1: Alternate day therapy

Three equal doses of **HuMoG**[®] are given On Alternate Days. In menstruating woman the initial dose of **HuMoG**[®] should be given on day 7, 8, or 9 of the cycle. A single dose of **HuCoG**[®] 10000 I.U. is given one week after the first injection of **HuMoG**[®] provided the clinical and biochemical responses are adequate and not excessive.

Schedule 2: Daily therapy

Daily. Injections of **HuMoG**[®] are given until an adequate response is achieved. This is judged on the basis of daily oestrogen determinations. In the absence of a response, the dose of **HuMoG**[®] may be increased or the course abandoned. A single **HuCoG**[®] Injection of 10000 I.U. is administered 24-28 hours after the last dose of **HuMoG**[®].

Schedule 2 is most commonly used.

Men:

Treatment should begin with **HuCoG**[®] 2000 I.U. 2-3 times a week to produce evidence of adequate masculinisation. If the response to **HuCoG**[®] is only androgenic, **HuCoG**[®] (1 vial 3 times a week) and **HuCoG**[®] 2000 I.U. (twice a week) are required to be administered.

CONTRA-INDICATIONS AND WARNINGS :

Women:

HuMoG[®] therapy is precluded when an effective response cannot be obtained e.g. Ovarian dysgenesis, Absence of uterus, Premature menopause, Tubular occlusion.

Men:

Patients with elevated endogenous FSH levels indicative of primary testicular failure are usually unresponsive to **HuMoG**[®] and **HuCoG**[®] therapy. Appropriate treatment should first be given for hypothyroidism, adrenocortical deficiency, hyperprolactinaemia or pituitary tumour. An acceptable semen analysis should be available before **HuMoG**[®] treatment.

Adherence to the recommended dosage and monitoring schedules will minimise the possibility of ovarian hyperstimulation. Excessive oestrogenic response to **HuMoG**[®] do not generally give rise to significant side effects unless **HuCoG**[®] is given to induce ovulation. Hormone assays will detect an excessive oestrogen response

to **HuMoG**[®] and **HuCoG**[®]. In such cases **HuMoG**[®] administration should be withheld. The incidence of multiple births following **HuMoG**[®] / **HuCoG**[®] therapy has been variously reported between 10% and 40%. However, the majority of multiple conceptions are twins.

Pregnancy loss due to spontaneous abortion is higher than in a normal population but are comparable with the rates in woman with other fertility problems. The risks of congenital abnormalities are not increased by **HuMoG**[®]

SIDE EFFECTS:

In the female, a local reaction at the injection site, fever and arthralgia have been observed in rare cases. In male, a combined treatment with **HuMoG**[®] and **HuCoG**[®] may cause gynecomastia.

STORAGE:

Vials of **HuMoG**[®] should be stored between 2^o-8^oC. DO NOT FREEZE. Solution reconstituted should be used immediately. Add diluent for reconstitution. Discard any unused portion.

PRESENTATION:

HuMoG[®] is supplied in sterile lyophilized form as a white powder in vials containing 75 I.U. /150 I.U. each FSH and LH activity.

Each vial is accompanied by one ampoule of 1 ml. Sodium Chloride injection I. P.

Drugs should be stored out of reach of children.



Marketed in India by:
BHARAT SERUMS AND VACCINES LIMITED
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