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

Menotropins For Injection U.S.P.

(Human Menopausal Gonadotropin Injection)

HUMOG®

(Freeze Dried)
For Intramuscular Injection only

COMPOSITION :
Each vial contains :
Menotropins U.S.P. equivalent to activity of
Follicle stimulating Hormone ..... 75 I.U. / 150 I.U.
Luteinizing Hormone ..... 75 I.U. / 150 I.U.

Excipients & Stabilizers :
Mannitol I.P., Di-Sodium Hydrogen Phosphate dihydrate I.P.,
Sodium Dihydrogen Phosphate dihydrate I.P., Sucrose I.P.

Each vial of **HUMOG** is accompanied by an ampoule containing 1ml of Sodium Chloride Injection 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 of 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 Gonadotrophin) 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 Hypogonadotrophic hypogonadism.

DOSAGE AND ADMINISTRATION :
HUMOG is given by intramuscular injection.
Reconstitute powder of vial in 1ml of Sodium Chloride Injection I.P. provided in the pack immediately prior to use. Upto 5 vials of **HUMOG** may be Reconstituted in 1 ml of Sodium Chloride Injection. Reconstituted solution should be used immediately after preparation. Any unused portion of solution should be discarded.

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 level is less than either 180nmol/24 hr. (50µg/24 hr) for tested urinary oestrogen or 1100pmol/L (300pg/ml) for plasma 17ß-oestradiol, follicular development may be inadequate. Conversely, if the levels are higher than either 514nmol/24 hr (140µg/24 hr) for total urinary oestrogens or 3000pmol/L (800pg/ml) for plasma 17ß-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 17ß-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.
If the patient wishes to conceive, she is recommended to have coitus on the day when **HUCOG** is given and on the following day. The dose of **HUMOG** required to evoke the desired response is critical and varies both from patient to patient and in the same patient at different times. Monitoring by hormones assay is therefore essential.

Two dosage schedules may 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, **HUMOG** (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 avaliable 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 wastes by abortion is higher than in a normal population but 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 the male, a combined treatment with **HUMOG** and **HUCOG** may cause gynecomastia.

STORAGE :
Vials of **HUMOG** should be stored between 2^0C - 8^0C. Do not freeze. Protect from light.
Reconstituted solution of **HUMOG** should be used immediately after preparation. Discard any unused portion.

PRESENTATION :
HUMOG is supplied in vial containing sterile, freeze dried white powder having 75 I.U. / 150 I.U. activity of each FSH and LH . Each vial is accompanied by an ampoule containing 1ml of Sodium Chloride Injection I.P.

Manufactured in India by :
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