

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

## Menotrophin For Injection B.P.

**HUMOG<sup>®</sup>**  
**75 HP / 150 HP**

### Highly Purified Menotrophin for Injection

#### Freeze Dried

For Subcutaneous / Intramuscular Injection Only

#### Composition :

Each vial contains :

Menotrophin B.P. equivalent to activity of

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

Luteinizing Hormone ..... 75 I.U. / 150 I.U.

#### Excipients :

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

Each vial of **HUMOG HP** contains Highly Purified Menotrophin and each vial is accompanied by an ampoule of Sodium Chloride Injection I.P. 1ml.

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 HP** (Human Menopausal Gonadotropin) is a hormonal substance containing FSH and LH in a ratio of 1:1. In the female, **HUMOG HP** 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 HP** stimulates the spermatogenesis by acting on the production of the androgen-binding protein in the seminiferous tubules of the sertoli cells.

#### Indications :

##### Women :

**HUMOG HP** and subsequently **HUCOG HP** (Human Chorionic Gonadotrophin) are indicated for the induction of ovulation in the amenorrhoeic patient or anovulatory women with regular or irregular cycles.

##### Men :

**HUMOG HP** with concomitant **HUCOG HP** therapy is indicated for the stimulation of spermatogenesis in men who have primary or secondary Hypogonadotrophic hypogonadism.

#### Dosage and Administration :

**HUMOG HP** is given by subcutaneous / intramuscular injection only.

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 HP** 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 HP** over several days and to give **HUMOG HP** 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 HP** 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 17β-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 17β-oestradiol, there is an increased risk of ovarian hyperstimulation and **HUCOG HP** should be withheld. The optimal time for **HUCOG HP** administration is the day of the urinary oestrogen peak or the day after the plasma 17β-oestradiol peak. In the anovulatory patient the stimulated follicles will not liberate ova spontaneously. Follicular rupture had to be achieved by injecting **HUCOG HP** 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 HP** is given and on the following day. The dose of **HUMOG HP** 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 HP** are given on alternate days. In menstruating woman the initial dose of **HUMOG HP** should be given on day 7, 8 or 9 of the cycle. A single dose of **HUCOG HP** 10000 I.U. is given one week after the first injection of **HUMOG HP**, provided the clinical and biochemical responses are adequate and not excessive.

**Schedule 2 : Daily therapy**

Daily injections of **HUMOG HP** 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 HP** may be increased or the course abandoned. A single **HUCOG HP** injection of 10000 I.U. is administered 24 - 28 hours after the last dose of **HUMOG HP**. Schedule 2 is most commonly used.

**Men :**

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

**Contra-Indications and Warnings :****Women :**

**HUMOG HP** 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 HP** and **HUCOG HP** therapy.

Appropriate treatment should first be given for hypothyroidism, adrenocortical deficiency, hyperprolactinaemia or pituitary tumour. An acceptable semen analysis should be available before **HUMOG HP** treatment.

Adherence to the recommended dosage and monitoring schedules will minimise the possibility of ovarian hyperstimulation. Excessive oestrogenic response to **HUMOG HP** do not generally give rise to significant side effects unless **HUCOG HP** is given to induce ovulation. Hormone assays will detect an excessive oestrogen response to **HUMOG HP** and **HUMOG HP**. In such cases **HUMOG HP** administration should be withheld. The incidence of multiple births following **HUMOG HP** / **HUCOG HP** 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 HP**.

**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 HP** and **HUCOG HP** may cause gynecomastia.

**Storage :**

Vials of **HUMOG HP** should be Store between 2<sup>0</sup>C - 8<sup>0</sup>C. Do not freeze. Protect from light. Reconstituted solution of **HUMOG HP** should be used immediately after preparation. Discard any unused portion.

**Presentation :**

**HUMOG HP** 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 :

**BHARAT SERUMS AND VACCINES LIMITED**

Plot No. K-27, Additional M.I.D.C., Ambernath (E) - 421 501