SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT :

HUMOG 75 HP [Menotrophin for Injection B.P. 75 IU (Highly Purified)]

2. QUALITATIVE AND QUANTITATIVE COMPOSITION :

Each vial contains : Menotrophin B.P. equivalent to activity of

Follicle-Stimulating Hormone ..... 75 I.U.

Luteinizing Hormone ..... 75 I.U.

Qualitative and quantitative composition of HUMOG 75 HP.

Names of Ingredients	**Unit and/or Percentage Formula**	**Function**	**Reference to Standards**
Active Substance(s)			
Menotrophin (Highly Purified)	75 IU	Active ingredient	BP
Excipient(s)			
Mannitol	30.0 mg	Bulking agent	BP
Sucrose	10.0 mg	Protein Stabilizer	BP
Anhydrous Disodium Hydrogen Phosphate	1.42 mg	pH Maintenance	BP
Sodium ascorbate	0.1 mg	Antioxidant	BP
Phosphoric Acid	--	pH adjustment	BP
Sodium Hydroxide	--	pH adjustment	BP
Water for Injection	--	Solvent	USP

3. PHARMACEUTICAL FORM:

Dosage form: Freeze dried powder for Injection.

Description: White powder or cake.

4. CLINICAL PARTICULARS:

4.1 Therapeutic 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.

4.2 Posology and method of administration

HUMOG HP is given by subcutaneous / intramuscular injection only. Reconstitute powder of vial in 1ml of Sodium Chloride Injection B.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 B.P. 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 Graqfian follicle with individually tailored doses of **HUMOG HP** over several days and to give **HuCoG 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 17ß-oestradiol, follicular development may be inadequate. Conversely, if the levels are higher than either 514nmol/24 hr (140µg/24 hr) for total urinary oestrogen or 3000pmol/L (800pg/ml) for plasma 17ß-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 17ß-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 hormone 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.

4.3 Contraindications:

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 **HuCoG 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 are 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**.

4.4 Special warnings and precautions for use

Refer **4.3 Contraindications.**

4.5 Interaction with other medicinal products and other forms of interaction: No clinically significant drug/drug or drug/food interactions have been reported during **HUMOG HP** therapy.

4.6 Use in pregnancy and lactation:

HUMOG HP should not be given if pregnancy is suspected or to lactating mothers.

4.7 Effects on ability to drive and use machines

No studies on the effects on ability to drive and use machines have been performed.

4.8 Undesirable 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 (Chorionic Gonadotropin Injection) may cause gynecomastia.

4.9 Overdoses

The effect of an overdose is unknown, nevertheless one could expect ovarian hyperstimulation syndrome to occur.

5. CLINICAL PHARMACOLOGY:

Pharmacotherapeutic group: human menopausal gonadotrophin, ATC code: G03GA02

HUMOG HP (Human Menopausal Gonadotrophin) is a hormonal substance containing FSH and LH in a ratio of 1:1. In 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.

6. PHARMACEUTICAL PARTICULARS :

6.1 List of excipients:

- Mannitol

- Sucrose
- Anhydrous Disodium Hydrogen Phosphate
- Sodium ascorbate
- Phosphoric Acid
- Sodium Hydroxide
- Polysorbate 20 (Tween 20)

6.2 Incompatibilities:

The product is stable and there is no incompatibility amongst excipients.

6.3 Shelf life :

36 months.

6.4 Special precautions for storage:

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

6.5 Nature and contents of container:

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

6.6 Special precautions for disposal

Not applicable

7. APPLICANT/MANUFACTURER:

Applicant:

Bharat Serums & Vaccines Ltd.
3rd Floor, Liberty Tower, Plot No. K-10,
Behind Reliable Plaza, Kalwa Industrial Estate, Airoli,
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Manufactured by:

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