

HIGHLY PURIFIED Inceptova[®] HMG Menotropin for Injection



Description¹

Inceptova HMG (Menotropin for injection, IP) is a preparation of gonadotropins, extracted from the urine of postmenopausal women which has undergone additional steps for purification. Each vial of **Inceptova HMG** contains 75/150 IU of FSH activity and 75/150 IU of LH activity. The biological activity of **Inceptova HMG** is determined using the BP bio-assays for FSH (ovarian weight gain assay in female rats) and LH (seminal vesicle weight gain assay in male rats), modified to increase the accuracy and reproducibility of these assays.

Composition

Each vial of sterile freeze-dried product contains:

Menotropin IP

Equivalent to the activity of

- | | |
|-------------------------------------|-------|
| • FSH | 75 IU |
| • LH | 75 IU |
| • Mannitol IP | q.s |
| • Potassium dihydrogen phosphate BP | q.s |
| • Dipotassium hydrogen phosphate BP | q.s |

Menotropin IP

Equivalent to the activity of

- | | |
|-------------------------------------|--------|
| • FSH | 150 IU |
| • LH | 150 IU |
| • Mannitol IP | q.s |
| • Potassium dihydrogen phosphate BP | q.s |
| • Dipotassium hydrogen phosphate BP | q.s |

Indications and Dosage

Indications Selection of Patients

- A thorough gynecologic and endocrine evaluation including an assessment of pelvic anatomy must be performed before treatment with **Inceptova HMG**. Patients with tubal obstruction should receive **Inceptova HMG** only if enrolled in an IVF program.
- Primary ovarian failure should be excluded by the determination of gonadotropin levels.

- Careful examination should be made to rule out the presence of an early pregnancy.
- Patients in late reproductive life have a greater predilection to endometrial carcinoma as well as a higher incidence of anovulatory disorders. A thorough diagnostic evaluation should always be performed in patients who demonstrate abnormal uterine bleeding or other signs of endometrial abnormalities before starting **Inceptova HMG** therapy.
- Evaluation of the partner's fertility potential should be included in the work-up.

Dosage

ART: The recommended initial dose of **Inceptova HMG** for patients who have received a GnRH agonist for pituitary suppression is 225 IU. Based on clinical monitoring (including serum estradiol levels and vaginal ultrasound results), subsequent dosing should be adjusted according to individual patient response. Adjustments in dose should not be made more frequently than once every 2 days and should not exceed 150 IU per adjustment. The maximum daily dose of **Inceptova HMG** given should not exceed 450 IU and dosing beyond 20 days is not recommended. Once adequate follicular development is evident, HCG should be administered to induce final follicular maturation in preparation for oocyte retrieval. The administration of HCG must be withheld in cases where the ovaries are abnormally enlarged on the last day of therapy. This should reduce the chance of developing Ovarian Hyper Stimulation Syndrome (OHSS).

Administration

Dissolve the contents of the vial of **Inceptova HMG** in 1 mL of sterile saline and administer either intramuscularly or subcutaneously immediately. Any unused reconstituted material should be discarded.

Side-Effects

- General – Pain / rash at injection site, headache, malaise
- Gastrointestinal – Nausea, vomiting, abdominal pain, bloating
- Urogenital – Breast tenderness, hot flushes, OHSS (in susceptible individuals)

Warnings

Inceptova HMG is a drug that should only be used by physicians who are thoroughly familiar with infertility problems.

Overstimulation of the Ovary during Inceptova HMG

Ovarian Enlargement: Mild to moderate uncomplicated ovarian enlargement which may be accompanied by abdominal distension and/or abdominal pain occurs in approximately 5–10% of women treated with Menotrophin and HCG and generally regresses without treatment within 2 or 3 weeks. The lowest dose consistent with expectation of good results and careful monitoring of ovarian response can further minimize the risk of overstimulation. If the ovaries are abnormally enlarged on the last day of **Inceptova HMG** therapy, HCG should not be administered in this course of treatment. This will reduce the chances of development of the OHSS.

Precautions

Laboratory Tests: The combination of both estradiol level ultrasonography is useful for monitoring the growth and development of follicles, timing HCG administration as well as minimizing the risk of the OHSS and multiple gestations.

The clinical confirmation of ovulation is determined by:

- A rise in basal body temperature; increase in serum progesterone and menstruation following the shift in basal body temperature.

When used in conjunction with indices of progesterone production, sonographic visualization of the ovaries will assist in determining if ovulation has occurred. Sonographic evidence of ovulation may include the following:

- Fluid in the cul-de-sac; ovarian stigmata and collapsed follicle.

Pregnancy and Lactation

- Menotrophin are not to be used in pregnancy. Clinical studies have not established as to whether Menotrophin are secreted in breast milk.
- Pediatric patients: Safety and effectiveness in pediatric patients have not been established.
- Geriatric patients: Safety and effectiveness in geriatric patients have not been established.

Overdosage

Aside from possible ovarian hyperstimulation, little is known concerning the consequences of acute overdosage with Menotrophin.

Contraindications

Inceptova HMG is contraindicated in women who have:

A high FSH level indicating primary ovarian failure; uncontrolled thyroid and adrenal dysfunction; an organic intracranial lesion such as a pituitary tumor; sex hormone dependent tumors of the reproductive tract and accessory organs; abnormal uterine bleeding of undetermined origin; ovarian cysts or enlargement not due to PCOS; prior hypersensitivity to Menotrophin or **Inceptova HMG**; **Inceptova HMG** is not indicated in women who are pregnant.

Storage Conditions

Store between 2°C to 8°C.

Do not freeze.

Use Immediately after reconstitution.

After reconstitution of **Inceptova HMG**, do not store if the reconstituted solution is not used. Discard the portion.

™ Trade Mark

Marketed by:



Human Biologicals Institute
(A Division of Indian Immunologicals Limited)

Manufactured by:

Sanzyme (P) Ltd.
Plot No. 8, Sy. No. 542, Koltur (V),
Shamirpet (M), Medchal-Malkajgiri (Dist.),
500101, Telangana, INDIA.