



Meno-clair®

HP-HMG 75IU - 150IU

Highly Purified



Our key technologies sophisticated manufacturing systems according to the highest quality and technical standards for special protein and hormones purification and separation methods.



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HP-HMG 75IU - 150IU

- ① Highly Purified Human Menopausal Gonadotropin (HP-HMG)
- ① Production and purification techniques according to the British Pharmacopeia⁽¹⁾
- ① 75IU - 150 IU for Intramuscular or Subcutaneous Use

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

MENO-CLAIR[®] HP-HMG

Description:

Each ampoule of MENO-CLAIR HP-HMG contains:

Highly Purified Human Follicle Stimulating Hormone (FSH) 75 or 150 I.U.

Highly Purified Human Luteinising Hormone (LH) 75 or 150 I.U. (as a freeze dried, sterile and pyrogen free powder). Each ampoule of MENO-CLAIR HP-HMG is accompanied by an ampoule of solvent containing 1 ml of isotonic, sterile and pyrogen free, Sodium Chloride.

Properties:

Highly Purified Human Menopausal Gonadotrophin (HP-HMG) is a hormonal substance containing HP-FSH and HP-LH in a ratio of about 1 : 1. In the female, MENO-CLAIR HP-HMG stimulates the growth and the maturation of ovarian follicles. It also induces an increase in the oestrogen levels and proliferation of the endometrium. In males, MENO-CLAIR HP-HMG stimulates spermatogenesis by acting on the production of androgen binding protein in the seminiferous tubules of the Sertoli cells.

Indications:

1. Follicle stimulation in females with Anovulatory Infertility.
2. Stimulation of spermatogenesis in males with oligospermia.

Dosage and Administration:

MENO-CLAIR HP-HMG is given by subcutaneous or intramuscular injection.

The powder in the ampoule should be reconstituted with the solvent provided just prior to use.

Two dosage schedules may be employed.

Schedule 1. Alternative day therapy:

Three equal doses of MENO-CLAIR HP-HMG are given on alternate days, in the first half (proliferative phase) of the menstrual cycle. This is followed by a single dose of 5 000 I.U. HP-HCG. HP-HCG given one week after the first injection of MENO-CLAIR HP-HMG provided the clinical and biochemical responses are adequate and not excessive.

Schedule 2. Daily therapy:

Daily injection of MENO-CLAIR HP-HMG is given until an adequate response is achieved. This is judged on the basis of daily oestrogen determinations or Sonography. In the absence of a response the dose of MENO-CLAIR HP-HMG may be increased or the course may have to be abandoned. A single injection of 5 000 to 10 000 I.U. HP-HCG is administered 24 to 48 hours after the last dose of MENO-CLAIR HP-HMG.

Schedule 2 is most commonly used:

In females, MENO-CLAIR HP-HMG therapy is precluded when an effective response cannot be obtained. The reasons could be because of ovarian dysgenesis, premature menopause, tubal occlusion etc.

If detected, appropriate treatment should first be given for hypothyroidism, adrenocortical deficiency, hyperprolactinaemia or a pituitary tumour. Adherence to the recommended dosage and monitoring schedules will minimize the possibility of ovarian hyperstimulation. Excessive oestrogenic response to MENO-CLAIR HP-HMG does not generally give rise to significant side effects unless HP-HCG is given to induce ovulation. Hormone assays can detect an excessive oestrogenic response to MENO-CLAIR HP-HMG and if positive, HP-HCG administration should then be withheld. The incidence of multiple births following MENO-CLAIR HP-HMG/HP-HCG therapy has been reported to be between 10% & 40%. However, the majority of multiple conceptions are twins. Pregnancy wastage by abortion is higher than in a normal population but comparable with rates in women with other fertility problems. The risks of congenital abnormalities are not increased by MENO-CLAIR HP-HMG.

IN MALES:

In the treatment of oligospermia 1 ampoule of MENO-CLAIR HP-HMG is given 3 times a week in combination with HP-HCG 2000 I.U., 2 – 3 times a week. The combined therapy should continue for at least 4 months.

In men, elevated androgenous /FSH levels are indicative of primary testicular failure. Such patients are usually unresponsive to MENOCLAIR HP-HMG/HP-HCG therapy.

How supplied:

Boxes of one ampoule freeze dried, sterile powder with one ampoule solvent.

Storage:

Should be stored between 2 – 8 °C and protected from light. The reconstituted solution should be used immediately after preparation.

Licenceholder:

N.V. Phare Belgium S.A.

Belgium

Manufactured by

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(1) Product monograph



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