

UROFOLLITROPHIN FOR INJECTION B.P. (FSH)

karma-FSH

(FREEZE DRIED)

For Intramuscular Injection only

COMPOSITION:

Each vial of karma-FSH contains:

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

Added substance: Mannitol B.P.

Di-sodium Hydrogen Phosphate B.P.

Sodium Dihydrogen Phosphate B.P.

Each vial of karma-FSH is accompanied by a solvent ampoule containing 1 ml of isotonic, sterile and pyrogen free Sodium Chloride Injection B.P.

PROPERTIES:

karma-FSH contains a purified hormone obtained from Human Menopausal urine having 75 I.U. / 150 I.U. FSH activity and less than 1 I.U. / 2 I.U. Luteinizing Hormone activity per vial. Human menopausal gonadotrophins (HMG) exerts both FSH and LH activities. For this reason, HMG is indicated in Hypogonadotrophic hypopituitarism (WHO Group I patients), where both gonadotrophin stimulations are needed.

In patients showing normal or high LH levels (WHO Group II), require preparations without LH activity, this character belongs to FSH.

FSH stimulates both the growth and maturation of follicles, it induces secretion of oestrogens and proliferation of the endometrium.

INDICATIONS:

karma-FSH and Human Chorionic Gonadotrophin (HCG) given in a sequential manner are indicated for induction of ovulation in patients with Polycystic Ovarian Disease (PCOD) who have an elevated LH / FSH ratio and who have failed to respond to adequate clomiphene citrate therapy.

karma-FSH and HCG may also be used to stimulate the development of multiple oocytes in ovulatory patients participating in an in vivo fertility program.

CONTRA-INDICATIONS:

karma-FSH is contra-indicated in women who exhibit:

1. High levels of FSH indicating primary ovarian failure
2. Uncontrolled thyroid or adrenal dysfunction
3. An organic intracranial lesion such as pituitary tumor
4. The presence of any cause of infertility other than anovulation as stated in indications unless they are candidates for in vitro fertilization.
5. Ovarian cysts or enlargement not due to ovarian polycystic Ovarian Disease.
6. Prior hypersensitivity to Urofollitrophin.
7. karma-FSH is contra-indicated in women who are pregnant. There are limited human data on the effects of karma-FSH when administered during pregnancy.

WARNING:

karma-FSH is a drug that should be used by Physicians who are thoroughly familiar with infertility problems.

1. karma-FSH should be used only with appropriate monitoring facilities.
2. Lowest dose consistent with expectation of good result should be used.

Ovarian response should be carefully monitored to minimize the risk of overstimulation.

If the ovaries are abnormally enlarged on last day of karma-FSH therapy, HCG should not be administered in this course therapy. This reduces development of OHSS (Ovarian Hyperstimulation Syndrome).

DOSAGE & ADMINISTRATION:

Dosage:

The dose of karma-FSH to produce maturation of the Follicle must be individualized for each patient.

It is recommended that initial dose to any patient should be 75 I.U. of karma-FSH per day administered intramuscularly for 7-12 days followed by HCG 5000 I.U. to 10000 I.U. one day after the last dose of karma-FSH.

Administration of karma-FSH may exceed 12 days if inadequate Follicle development is indicated by oestrogen and/or ultrasound measurements.

If there is evidence of ovulation but no pregnancy repeat this dosage regimen for at least 2 or more courses before increasing the dose to 150 I.U. FSH per day for 7-12 days. As before this dose should be followed by 5000 I.U. to 10000 I.U. of HCG one day after last dose of karma-FSH. If evidence of ovulation is present but pregnancy dose not ensure repeat the same dose for 2 more courses. Doses larger than this are not routinely recommended.

In-vitro Fertilization:

In-vitro Fertilization therapy with karma-FSH should be initiated in the early follicular phase (cycle day 2 or 3) at a dose of (150 I.U. per day) until sufficient Follicular development is attained. In most cases therapy should not exceed beyond 10 days.

Administration:

Dissolve the contents of one vial of karma-FSH in 1 ml of Sodium Chloride Injection and administer intramuscularly immediately. Any unused reconstituted material should be discarded.

STORAGE:

Vials of karma-FSH Injection should be stored between 2°C–8°C and protected from light. Do not freeze. Solution of karma-FSH reconstituted in Sodium Chloride Injection should be used immediately after preparation. Discard any unused portion.

PRESENTATION:

karma-FSH is supplied in a sterile lyophilized form as a white to off-white powder in vials containing 75 I.U. FSH activity / 150 I.U. FSH activity, accompanied by a solvent ampoule containing 1 ml of Sodium Chloride Injection B.P.

Keep out of reach of children.

Manufactured by:



Marketed by:

