FOLISURGE 75/150

Recombinant Human Follicle Stimulating Hormone (Follitropin alfa, r-Hu FSH) solution for injection. It is a human follicle stimulating hormone (FSH) preparation of recombinant DNA origin. Composition of Recombinant Human Follicle Stimulating Hormone (Follitropin alfa, r-Hu FSH) Drug Product In Prefilled Syringe: Each prefilled syringe delivers 75 IU of r-Hu FSH per 0.12 ml or 150 IU of r-Hu FSH per 0.24 ml. Excipients: Each ml contains 0.45 mg monosodium dihydrogen phosphate monohydrate, 1.11 mg disodium hydrogen phosphate dihydrate, 5.8 mg sodium chloride, 0.1 mg polysorbate 20, orthophosphoric acid*, sodium hydroxide* and water for injection.-for adjustment of Ph. Apart from ingredients mentioned above certain sugars such as Mannitol, Trehalose dihydrate, L-Methionine and salt are used as stabilizers. Indication: Anovulation (including polycystic ovarian disease, PCOD) in women who have been unresponsive to treatment with Clomiphene citrate. Controlled ovarian hyper stimulation to induce the development of multiple follicles in medically assisted reproduction programmes (e.g. In vitro fertilization-embryo transfer (IVF ET), gamete intrafallopian transfer (GIFT) and intracytoplasmic sperm injection (ICSI). In association with a Luteinizing hormone (LH) preparation is recommended for the stimulation of Follicular development in women with severe LH & FSH deficiency. In clinical trials these patients were defined by an endogenous serum LH level < 1.21U/L. It is indicated for the stimulation of spermatogenesis in men who have congenital or acquired hypogonadotrophic hypogonadism with concomitant human Chorionic Gonadotrophin (hCG) therapy. Dosage: Individualized for each patient. (Administration: subcutaneously): Induction of ovulation in Infertile Patients with oligo-anovulation: The lowest dose consistent with the expectation of good results should be used. Commence within first 7 days of the menstrual cycle. A commonly used regimen starts at 75-150 IU r-Hu FSH daily. Initial dose of the first cycle: 751U /day, subcutaneously. An increase in dose by 37.5 IU may be considered after or 14 day intervals if necessary. Should be administered until adequate follicular development is achieved. Maximum dose: not higher than 225IU r-Hu FSH per day. If a patient fails to respond adequately after 4 weeks of treatment, that cycle should be abandoned. The patient should undergo further evaluation after which she may recommence treatment at a higher starting dose than in the abandoned cycle. Recombinant human choriogonadotropin alfa (r-hCG) or 5,000/10000 IU of hCG should be administered 1 day after last follitropin alfa (rHu FSH) injection. Ovarian stimulation for multiple follicular development prior to in vitro fertilization or other assisted reproductive technologies: Follitropin alfa is started when down regulation is achieved, 150-225 IU Follitropin alfa/day are administered for the first 5 to 7 days. In women 35 years of age and whose endogenous gonadotropin levels are suppressed, initiate Follitropin alfa administration at a dose of 225 IUs per day.The dose Is adjusted according to the ovarian response no more frequently than every 3-5 days and by no more than 75-150 IU additionally at each adjustment. GnRH agonist and follitropin alfa are continued until adequate follicular development is achieved. Maximum dose : 450 IU per day. A single injection of 250 micrograms r-hCG or 5,000 IU up to 10,000 IU hCG is administered 24-48 hours after the last follitropin alfa (rHu FSH) injection to induce final follicular maturation. Along with LH preparation for follicular development in women with severe LH & FSH deficiency: Start with 751U of lutropin alfa daily with 75-150 IU rHu FSH . If an FSH dose increase is required, it should be after 7- 14 day intervals by 37.5-75 IU increments. The treatment will be continued until adequate follicular development is achieved. The duration of stimulation may extend to up to 5 weeks. When an optimal response is obtained, a single injection of 250 micrograms r-hCG or 5,000 IU up to 10,000 IU hCG should be administered 24-48 hours after the last follitropin alfa (rHu FSH) and lutropin alfa injections. The patient is recommended to have coitus on the day of, and on the day following, hCG administration or intrauterine insemination may be performed. Luteal phase support may be recommended. If an excessive response is obtained, treatment should be stopped and hCG withheld. Treatment should restart in the next cycle at a dose of FSH lower than that of the previous cycle. Men with hypogonadotrophic hypogonadism: Follitropin alfa (rHu FSH) should be given at a dose of 150 IU three times a week, concomitantly with hCG, for a minimum of 4 months. If after this period, the patient has not responded, the combination treatment (Follitropin alfa (rHu FSH) with hCG) may be continued. Treatment for at least 18 months may be necessary to achieve spermatogenesis.Method of administration: Follitropin alfa (rHu FSH) is intended for subcutaneous administration. The first injection of Follitropin alfa (rHu FSH) should be administered under direct medical supervision. Suitable site for subcutaneous administration is in the abdomen. The solution should not be administered if it contains particles or is not clear. The prefilled syringe is for single use. Contraindications: In women-Hypersensitivity to the active substance follitropin alfa, FSH or to any of the excipients, Tumours of the hypothalamus or pituitary gland, Ovarian enlargement or ovarian cyst not due to polycystic ovarian syndrome, Gynecological hemorrhages of unknown etiology, Ovarian, uterine or mammary carcinoma, Pregnancy, Primary ovarian failure, Malformations of sexual organs incompatible with pregnancy, Fibroid tumors of the uterus incompatible with pregnancy. In Men: Primary testicular insufficiency, Hypersensitivity to the active substance follitropin alfa, FSH or to any of the excipients, Tumours of the hypothalamus or pituitary gland. Warnings and precautions; Follitropin alfa (r-Hu FSH) is a potent gonadotrophic substance, which can cause mild to severe adverse reactions. Porphyria: Patients with porphyria or a family history of porphyria should be closely monitored during treatment with Follitropin alfa (r-Hu FSH). In case of a first appearance or deterioration of this condition, the treatment with Follitropin alfa should be stopped. Treatment in women: Before starting treatment, the couple's infertility should be assessed and putative contraindications for pregnancy evaluated. In particular, patients should be evaluated for hypothyroidism, adrenocortical deficiency, hyperprolactinemia and appropriate specific treatment given. Patients undergoing stimulation of follicular growth, whether as treatment for anovulatory infertility or ART procedures, may experience ovarian enlargement or develop hyperstimulation. Adherence to recommended Follitropin alfa (r-Hu FSH) dose and regimen of administration and careful monitoring of therapy will minimize the incidence of such events. Ovarian Hyperstimulation Syndrome (OHSS): The risk of ovarian hyperstimulation can be minimized by adherence to recommended dose of Follitropin alfa (r-Hu FSH) and regimen of administration. Monitoring of stimulation cycles by ultrasound scans as well as oestradiol measurements are recommended to early identify risk factors. Independent risk factors for developing OHSS include polycystic ovarian syndrome high absolute or rapidly rising serum oestradiol levels (e.g. > 900 pg/ml or > 3,300 pmol/L in anovulation; > 3,000pg/ml or > 11,000 pmol/L in ART) and large number of developing ovarian follicles (e.g. > 3 follicles of ≥, 14 mm in diameter in anovulation; ≥ 20 follicles of ≥ 12 mm in diameter in ART).The administration of hCG must be withheld in cases where the ovaries are abnormally enlarged on the last day of Follitropin alfa therapy and the patient be advised to refrain from coitus or to use barrier contraceptive methods for at least 4 days. Ectopic pregnancy: Since infertile women undergoing assisted reproduction, and particularly IVF, often have tubal abnormalities the incidence of ectopic pregnancies with r-Hu FSH treatment might be increased. Early confirmation of an intrauterine pregnancy is therefore is important. Treatment in men: Elevated endogenous FSH levels are indicative of primary testicular failure. Such patients are unresponsive to Follitropin alfa (r-Hu FSH) /hCG therapy. Semen analysis is recommended 4 to 6 months after the beginning of treatment as part of the assessment of the response. Multiple pregnancy: In women undergoing induction of ovulation & ART with gonadotrophin, there is an increased risk of multiple gestations. In ART the risk is related mainly to the number of embryos replaced, their quality and the patient age. To minimize the risk of multiple pregnancy, careful monitoring of ovarian response is recommended. Pregnancy loss: The incidence of pregnancy loss by miscarriage is higher in patients undergoing ovulation induction or ART than following natural conception. Reproductive system neoplasms: There have been reports of ovarian and other reproductive system neoplasms, both benign and malignant, in women who have undergone multiple treatment regimens for infertility treatment. It is not yet established whether or not treatment with gonadotropins increases the risk of these tumours in infertile women. Congenital malformation: Because of differences in parental characteristics (e.g. maternal age, sperm characteristics) and multiple pregnancies, the prevalence of congenital malformations after ART may be slightly higher than after spontaneous conceptions. Thromboembolic events: In women with recent or ongoing thromboembolic disease or women with risk factors for thromboembolic events gonadotropins may further increase the risk for aggravation or occurrence of such events. Pregnancy itself as well as OHSS also carry an increased risk of thromboembolic events. Drug interactions: Concomitant use of follitropin alfa with other drugs used to stimulate ovulation (e.g. hCG, clomiphene citrate) may potentiate the follicular response. Concurrent use of a GnRH agonist or antagonist to induce pituitary desensitization may Increase the dose of Follitropin alfa required. No other clinically significant drug Interaction has been reported. Shelf life: 24 Months Storage and handling instruction Store at 2 °C-8 °C (in a refrigerator). Do not freeze or shake. Keep out of reach and sight of children. The solution should not be administered if it contains particles or is not clear.
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(For the use of a registered medical practitioner or hospital or laboratory only)