STIMUFOL 75/150

(UROFOLLITROPIN FOR INJECTION BP 75/150 IU)

Composition: Each vial contains: Urofollitropin BP equivalent to activity of Follicle Stimulating Hormone (FSH) 75/150 IU Excipients Q.S. Indications Urofollitropin for injection and hCG given in a sequential manner is indicated for the treatment of female infertility in the following clinical situations: Anovulation including polycystic ovarian disease (PCOD)} in women who have been unresponsive to treatment with clomiphene citrate. Controlled ovarian hyperstimulation to induce the development of multiple follicles for assisted reproductive technologies (ART) (e.g.in vitro Fertilisation embryo transfer (IVF ET),gamete intra-fallopian transfer (GIFT) and intracytoplasmic sperm injection (ICSI)} Dosage and administration Women with anovulation (including PCOD): The lowest dose consistent with the expectation of good results should be used. Treatment should commence within the first 7 days of the menstrual cycle. Urofoltilropin should be administered until adequate follicular development is indicated by serum estradiol and vaginal ultrasonography. It is recommended that the initial dose of the first cycle be 75 IU of Urofollitropin per day, administered subcutaneously or intramuscularly. An adjustment in dose may be considered after 5 to 7 days. An additional dose adjustment may also be considered based on individual patient response. The dose should not be increased more than twice in any cycle or by more than 75IU per adjustment. To complete follicular development and effect ovulation in the absence of an endogenous LH surge, Human chorionic gonadotropin (hCG 5,000 IU to 10,000 IU, should be given 1day after the last dose of urofollilropin for injection. The couple should be encouraged to have intercourse daily, beginning on the day prior to the administration of hCG until ovulation becomes apparent. Care should be taken to ensure insemination. If the ovaries are abnormally enlarged or abdominal pain occurs, Urofollitropin should be discontinued, hCG should not be administered, and the patient should be advised not have intercourse; this will reduce the chance of development of the Ovarian Hyperslimulalion Syndrome (OHSS) and, should spontaneous ovulation occur, reduce the chance of multiple gestation. The initial dose administered in the subsequent cycles should be based on response in the preceding cycle. Doses larger than 300 IU of FSH per day are not routinely recommended. Assisted Reproductive Technologies (ART): The dose of Urofollitropin to stimulate development of the follicle must be individualized for each patient. Urofollitropin be initialed in the early follicular phase {cycle day 2 or 3) at a dose of 150 IU per day .The initial dose for patients undergoing IVF who have received GnRH agonist or antagonist pituitary suppression is 150-225IU daily for the first 5 days of treatment. Based on clinical monitoring (including serum estradiol levels and vaginal ultrasound results) subsequent dosing should be adjusted according to individual patient response. The maximum daily dose given should not be higher than 450 IU daily. In most cases, therapy should not exceed twelve days. Method of administration & Directions for Reconstitution: Reconstitute with 1mlof Sodium Chloride Injection I.P.(0.9% w/v) provided. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration. Use immediately after reconstitution, administer by intramuscular or subcutaneous injection. Do not use the reconstituted solution if any visible particle is seen. Any unused solution should be discarded. Contraindications: women who exhibit: 1. High levels of FSH indicating primary ovarianfailure.2.Uncontrolled thyroid or adrenal dysfunction.3.An organic intracranial lesion such as a pituitary tumor.4. The presence of any cause of infertility other than anovulation, as staled in the 'Indications' unless they are candidates for ART. 5. Abnormal bleeding of undetermined origin.6.Ovariancysts or enlargement of undetermined origin.7. Prior hypersensitivity to urofollitropin 8 Urofollitropin for injection is also contraindicated in women who are pregnant women and may cause fetal harm when administered to a pregnant woman. Warnings and precautions: Urofollitropin is a potent gonadotropic substance capable of causing mild to severe adverse reactions. Therefore, the lowest dose consistent with the expectation of good results should be used. Monitor ovarian response with, serum estradiol and vaginal ultrasound, on a regular basis. It is not known whether this drug is excreted in human milk. Caution should be exercised if urofollitropin is administered to a nursing woman. Overstimulation of the ovary: Mild to moderate uncomplicated ovarian enlargement which may be accompanied by abdominal distension and/or abdominal pain occurs in some patients treated with Urofollitrophin and hCG, and generally regresses without treatment within two or three weeks. If the ovaries are abnormally enlarged on the last day of Urofollitropin therapy, hCG should not be administered. This will reduce the chances of development of the OHSS. The OHSS: Severe OHSS may progress rapidly (within 24 hours to several days) to become a serious medical event. It is characterized by an apparent dramatic increase in vascular permeability which can result in a rapid accumulation of fluid in the peritoneal cavity, thorax, and potentially the pericardium. The following symptomatology has been seen with cases of OHSS: abdominal pain, abdominal distension, gastrointestinal symptoms including nausea, vomiting and diarrhea, severe ovarian enlargement, weight gain, dyspnea, and oliguria. Clinical evaluation may reveal hypovolemia, hemoconcentration, electrolyte imbalances, ascites, hemoperitoneum, pleural effusions, hydrothorax, acute pulmonary distress, and thromboembolic events. Transient liver function test abnormalities suggestive of hepatic dysfunction have been reported in association with the OHSS. Therefore in cases of ovarian hyperstimulation is prudent to withhold hCG and advise the patient to refrain from coitus or to use barrier methods for at least 4 days. If severe OHSS occurs, treatment must be stopped and the patient should be hospitalized. A physician experienced in the management of this syndrome, should be consulted. Adverse drug reactions: Headache, Mild to moderate ovarian enlargement, abdominal pain, Sensitivity to urofollitropin (Febrile reactions which may be accompanied by chills, musculoskeletal aches, joint pains, malaise, headache, and fatigue) Ovarian cysts, Gastrointestinal symptoms (nausea, vomiting, diarrhea, abdominal cramps, bloating), Pain, rash, swelling, and/or irritation at the site of injection, Breast tenderness, Dermatological symptoms (dry skin, body rash, hair loss, hives), Ovarian Hyperstimulation Syndrome, Adnexal torsion, Pulmonary and vascular complications. There have been infrequent reports of ovarian neoplasms, in women who have undergone multiple drug regimens for ovulation induction; however, a causal relationship has not been established. Ectopic pregnancy and congenital abnormalities have been reported subsequent to pregnancies resulting from urofollitropin therapy, none of these events thought to be drug-related. The incidence does not exceed that found in the general population.

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(For the use of a registered medical practitioner or hospital or laboratory only)