

## **CORIOSURGE XP 2000/5000**

CORIOSURGE XP 2000/5000 Composition: Each vial contains: Human Chorionic Gonadotrophin IP 2000/5000 IU, Mannitol IP Q.S. Potassium Dihydrogen Phosphate BP Q.S., Dibasic Potassium Phosphate BP Q.S. Indications 1) Induction of ovulation in the anovulatory, infertile woman in whom the cause of anovulation is secondary and not due to primary ovarian failure, and who has been appropriately pretreated with FSH-containing preparation. 2) Prepubertal cryptorchidism not due to anatomical obstruction. In general, HCG is thought to induce testicular descent in situations when descent would have occurred at puberty. HCG thus may help predict whether or not orchiopexy will be needed in the future. Although, in some cases, descent following HCG administration is permanent, in most cases, the response is temporary. Therapy is usually instituted in children between the ages of 4 and 9. 3) Selected cases of hypogonadotropic hypogonadism (hypogonadism secondary to a pituitary deficiency) in males. Dosage and administration For intramuscular (I.M) or subcutaneous (S.C.) use only. The dosage regimen employed in any particular case will depend upon the indication for the use, the age and weight of the patient, and the physician's preference. The following regimens have been advocated by various authorities: Prepubertal cryptorchidism not due to anatomical obstruction. Therapy is usually instituted in children between the ages of 4 and 9. 1) 4,000 IU three times weekly for three weeks. 2) 5,000 IU every second day for four injections. 3) 15 injections for 500 to 1,000 IU over a period of six weeks. 4) 500 IU three times weekly for four to six weeks. If this course of treatment is not successful, another series is begun one month later, giving 1,000 IU per injection. Selected cases of hypogonadotropic hypogonadism in males: 500 to 1,000 IU three times a week for three weeks, followed by the same dose twice a week for three weeks. Induction of ovulation and pregnancy in the anovulatory infertile woman in whom the cause of anovulation is secondary and not due to primary ovarian failure and who has been appropriately pretreated with FSH containing preparation. 5,000 to 10,000 IU one day following the last dose of FSH-containing preparation. Method of administration & Directions for Reconstitution: Reconstitute with 1ml of 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 Precocious puberty, prostatic carcinoma or other androgen-dependent neoplasm, prior allergic reaction to HCG. Hypersensitivity to human gonadotropins or any of the excipients. Adverse drug reactions; Headache, irritability, restlessness, depression, fatigue, edema, precocious puberty, urticaria, gynecomastia, pain and/or rash at the site of injection. Warnings and precautions: HCG should be used in conjunction with human gonadotropins only by physicians experienced with infertility problems who are familiar with the criteria for patient selection, contraindications, warnings, precautions and adverse reactions. The principal serious adverse reactions during this use in women are: (1) Ovarian hyperstimulation, a syndrome of sudden ovarian enlargement, ascites with or without pain, and/or pleural effusion, (2) Rupture of ovarian cysts with resultant hemoperitoneum, (3) Multiple births, (4) Arterial thromboembolism, and (5) Anaphylaxis and other Hypersensitive Reactions. General: Since androgens may cause fluid retention, HCG should be used with caution in patients with cardiac or renal disease, epilepsy, migraine, or asthma. Pediatric Use Induction of androgen secretion by HCG may induce precocious puberty in pediatric patients treated for cryptorchidism. Therapy should be discontinued if signs of precocious puberty occur. Geriatric Use There is no any clinical trial data on subjects aged 65 and over for chorionic gonadotropin for injection.

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