Generic Name Size: 17 pt
Brand Name Size: 15 pt

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Chorionic Gonadotrophin Injection I.P. 5000 IU

IVFhCG 5000

Highly Purified I.M./S.C use only.

Combi-Pack Lyophilized.

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

1. Generic Name: Chorionic Gonadotrophin Injection I.P. 5000 IU

2. Composition:

Each Combi- Pack Contains

Chorionic Gonadotrophin Inj. I.P. 5000 IU (Combi-Pack)

Each vial contains:

(1) Chorionic Gonadotrophin I.P. .... 5000 I.U.
Mannitol I.P. ..... q.s.
Disodium hydrogen orthophosphate I.P. (as buffer)..... q.s.
Sodium Dihydrogen orthophosphate I.P. (as buffer)..... q.s.

(2) Sodium Chloride Injection I.P. 0.9% w/v. One ampoule of 2 ml

Each ml contains

Sodium Chloride I.P. 0.9 % w/v
Water for Injection I.P. ..... q.s.

3. Dosage Form and Strength: Chronic Gonadotrophin is supplied in glass vials containing sterile lyophilized powder equivalent to 5000 IU of Chronic Gonadotrophin.

4. Clinical Particulars

4.1 Indication

1. 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 between the ages 4 and 9.

2. Selected cases of hypogonadotropichypogonadism (hypogonadism secondary to a pituitary deficiency) in males.

3. 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 pre-treated with human menotropins.

4.2 Posology and Method of Administration

Intramuscular or Subcutaneous use only

The dosage regimen employed in any particular case will depend upon the indication for use, the ageand 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

1. 4,000 I.U. three times weekly for three weeks.

2. 5,000 I.U. every second day for four injections.

3. 15 injections of 500 to 1,000 I.U. over a period of six weeks.

4. 500 I.U. three times weekly for four to six weeks. If this course of treatment is not successful, another is begun one month later giving 1,000 I.U. per injection.

Selected Cases Of Hypogonadotropic Hypogonadism In Males

1. 500 to 1,000 I.U. three times a week for three weeks, followed by the same dose twice a week for three weeks.

2. 4,000 I.U. three times weekly for six to nine months, following which the dosage may be reduced to 2,000 I.U. three times weekly for an additional three months. 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 human menotropins (see prescribing information for menotropins for dosage and administration for that drug product). 5,000 to 10,000 I.U. one day following the last dose of menotropins. (A dosage of 10,000 I.U. is recommended in the labeling for menotropins.)

4.3 Contraindications

Precocious puberty, prostatic carcinoma or other androgen-dependent neoplasm, prior allergic reaction to HCG. Combined HCG/PMS (pregnant mare's serum) therapy has been noted to induce high incidences of external congenital anomalies in the offspring of mice, in a dose-dependent manner. The potential extrapolation to humans has not been determined.

4.4 Special Warnings and Precautions

HCG should be used in conjunction with human menopausal gonadotropins only by physicians experienced with infertility problems who are familiar with the criteria for patient selection, contraindications, warnings, precautions and adverse reactions described in the package insert formenotropins. The principal serious adverse reactions are: (1) Ovarian hyper stimulation, a syndrome of sudden ovarian enlargement, ascites with or without pain and/or pleural effusion, (2) Rupture of ovariancysts with resultant hemoperitoneum, (3) Multiple births and (4) Arterial thromboembolism. Anaphylaxis and other hypersensitivity reactions have been reported with urinary-derived HCGproducts.

General

Induction of androgen secretion by HCG may induce precocious puberty in patients treated for cryptorchidism. Therapy should be discontinued if signs of precocious puberty occur. Since androgens may cause fluid retention, HCG should be used with caution in patients with cardiac or renal disease, epilepsy, migraine or asthma.

Drug/Laboratory Test Interactions

Chorionic gonadotropin may interfere with radioimmunoassay for gonadotropins, particularly luteinizing hormone.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term studies in animals have not been performed to evaluate the carcinogenic or mutagenic potential of chorionic gonadotropin.

Pediatric Use

Safety and effectiveness of chorionic gonadotropin in children below the age of four have not been established.

Pregnancy

Teratogenic Effects: Pregnancy Category C– Chorionic gonadotropin may cause fetal harm when administered to a pregnant woman. Defects of forelimbs and central nervous system and alterations in sex ratio have been reported in mice receiving combined gonadotropin and chorionic gonadotropin therapy in dosages to induce super ovulation. Multiple ovulations with resulting plural gestations (mostly twins) have been reported to occur in approximately 20% of pregnancies when conception has followed chorionic gonadotropin therapy.

Nursing Mothers

It is not known whether chorionic gonadotropin is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when chorionic gonadotropin is administered to anursing woman.

4.5 Drug Interactions: NA

4.6 Use in Special Population

Impairment of Fertility: There have been sporadicreports of testicular tumors in otherwise healthy young men receiving HCG for secondary infertility. A causative relationship between HCG and tumor development in these men has not been established. Defects of forelimbs and of the central nervous system, as well asalterations in sex ratio, have been reported in mice on combined gonadotropin and HCG regimens. The dose of gonadotropin used was intended to induce super ovulation. Nomutagenic effect has been clearly established in humans.

Pregnancy: Teratogenic effects Combined HCG/PMS (pregnant mare's serum) therapy has been noted to induce high incidences of external congenital anomalies in the off springof mice, in a dose-dependent manner. The potential extrapolation to humans has not been determined.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when HCG is administered to a nursing woman.

Pediatric Use: Safety and effectiveness in children below the age of 4 have not been established.

4.7 Effect on Ability to Drive and Use Machines: NA

4.8 Undesirable Effects

Headache, irritability, restlessness, depression, fatigue, edema, precocious puberty, gynecomastia, pain at the site of injection. Hypersensitivity reactions both localized and systemic in nature, including erythema, urticaria, rash angioedema, dyspnea and shortness of breath, have been reported.

4.9 Overdose: NA

5. Pharmacological Properties

5.1 Mechanism of Action

The action of HCG is virtually identical to that of pituitary LH, although HCG appears to have a small degree of FSH activity as well. It stimulates production of gonadal steroid hormones by stimulating the interstitial cells (Leydig cells) of the testis to produce androgens and the corpus luteum of the ovary to produce progesterone. Androgen stimulation in the male leads to the development of secondary sex characteristics and may stimulate testicular descent when no anatomical impediment to descent is present. This descent is usually reversible when HCG is discontinued. During the normal menstrual cycle, LH participates with FSH in the development and maturation of the normal ovarian follicle, and the mid-cycle LH surge triggers ovulation. HCG can substitute for LH in this function. During a normal pregnancy, HCG secreted by the placenta maintains the corpus luteum after LH secretion decreases, supporting continued secretion of estrogen and progesterone and preventing menstruation.

6. Non-Clinical Properties

6.1 Animal Toxicology: NA

7. Description

Human chorionic gonadotropin (HCG), a polypeptide hormone produced by the human placenta, is composed of an alpha and a beta sub-unit. The alpha sub-unit is essentially identical to the alpha subunits of the human pituitary gonadotropins, luteinizing hormone (LH) and follicle-stimulating hormone (FSH), as well as to the alpha sub-unit of human thyroid-stimulating hormone (TSH). The beta sub-units of these hormones differ in amino acid sequence. Chorionic gonadotropin is obtained from the human pregnancy urine. It is standardized by a biological assay procedure.

8. Pharmaceutical Particulars

8.1 Incompatibilities: In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

8.2 Shelf Life: Please see manufacturing date & expiry date printed on the pack

8.3 Packaging Information: Chorionic Gonadotrophin is available in the form of lyophilized powder in vial with 2 ml ampoule of sodium chloride Inj I.P. 0.9% w/v solution as a solvent.

8.4 Storage and Handling Instructions: Should be stored below 20°C. Do not freeze. Protect from light & moisture. After reconstitution solution should be used immediately.

9. Patient Counselling Information: NA

10. Details of Manufacturer: Gufic Biosciences Limited

11. Details of Permission or Licence Number with Date: G/64.....01 JAN.2017

GUFIC®

Manufactured by:
Gufic Bioscience Ltd.N.H.No.8, Near Grid,Kabilpore-396 424, Navsari,Gujarat.

NEOVA BIOGENE

Marketed by:
Neova Biogene Pvt Ltd Monte Plaza,MM Malviya Marg Mulund(W),Mumbai-80.India.

Pack Insert Front Size: 150 mm x 200 mm