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Source : USFDA

CHORIONIC GONADOTROPIN

FOR INJECTION, USP

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 sub-units 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.

Chorionic Gonadotropin for Injection, USP is available in multiple dose vials containing 10,000 USP Units with accompanying Bacteriostatic Water for Injection for reconstitution. When reconstituted with 10 mL of the accompanying diluent each vial contains:

Chorionic gonadotropin	10,000 Units
Mannitol	100 mg
Benzyl alcohol	0.9%
Water for Injection	q.s.

Buffered with dibasic sodium phosphate and monobasic sodium phosphate. Hydrochloric acid and/or sodium hydroxide may have been used for pH adjustment (6.0-

8.0). Nitrogen gas is used in the freeze drying process.

CLINICAL PHARMACOLOGY:

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. HCG HAS NO KNOWN EFFECT ON FAT MOBILIZATION, APPETITE OR SENSE OF HUNGER, OR BODY FAT DISTRIBUTION.

INDICATIONS AND USAGE:

HCG HAS NOT BEEN DEMONSTRATED TO BE EFFECTIVE ADJUNCTIVE THERAPY IN THE TREATMENT OF OBESITY. THERE IS NO SUBSTANTIAL EVIDENCE THAT IT INCREASES WEIGHT LOSS BEYOND THAT RESULTING FROM CALORIC RESTRICTION, THAT IT CAUSES A MORE ATTRACTIVE OR ‘‘NORMAL’’ DISTRIBUTION OF FAT, OR THAT IT

DECREASES THE HUNGER AND DISCOMFORT ASSOCIATED WITH CALORIE-RESTRICTED DIETS.

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 four and nine.

2. Selected cases of hypogonadotropic hypogonadism (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 pretreated with human menotropins.

CONTRAINDICATIONS:

Precocious puberty, prostatic carcinoma or other androgen-dependent neoplasm, prior allergic reaction to HCG.

WARNINGS:

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 for menotropins. The principal serious adverse reactions

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 and (4) Arterial thromboembolism.

Anaphylaxis and other hypersensitivity reactions have been reported with urinary-derived hCG products.

PRECAUTIONS:

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 superovulation. 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 a nursing woman.

ADVERSE REACTIONS:

Headache, irritability, restlessness, depression, fatigue, edema, precocious puberty, gynecomastia and pain at the site of injection.

DOSAGE AND ADMINISTRATION:

Intramuscular Use Only

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

1. 4,000 USP Units three times weekly for three weeks.

2. 5,000 USP Units every second day for four injections.

3. 15 injections of 500 to 1,000 USP Units over a period of six weeks.

4. 500 USP Units 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 USP Units per injection.

Selected Cases Of Hypogonadotropic Hypogonadism In Males

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

2. 4,000 USP Units three times weekly for six to nine months, following which the dosage may be reduced to 2,000 USP Units 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 USP Units one day following the last dose of menotropins. (A dosage of 10,000 Units is recommended in the labeling for menotropins.)

IMPORTANT: USE COMPLETELY WITHIN 60 DAYS AFTER

RECONSTITUTION. REFRIGERATE AFTER RECONSTITUTION.

DIRECTIONS FOR RECONSTITUTION:

Two-Vial Package

Withdraw sterile air from lyophilized vial and inject into diluent vial. Remove 10 mL from diluent vial and add to lyophilized vial; agitate gently until solution is complete.

HOW SUPPLIED:

Chorionic Gonadotropin for Injection, USP, lyophilized, is supplied in two-vial packages including Bacteriostatic Water for Injection as diluent as follows:

Product No.	**NDC No.**	
25021	63323-025-10	Chorionic Gonadotropin for Injection, USP, 10,000 USP Units in a 10 mL multiple dose vial with accompanying diluent in packages of 10.

The product is assayed in accord with the USP method and potencies refer to USP Units (International Units) defined in terms of the USP Chorionic Gonadotropin Reference Standard.

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

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