



CHORIONIC GONADOTROPIN (HCG-5000 IU)

CHORIONIC GONADOTROPIN 5000 IU

Presented as box containing one vial with 5000 IU of CHORIONIC GONADOTROPIN in the form of injectable lyophilic powder.

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 5000 USP Units with accompanying Bacteriostatic Water for Injection for reconstitution. When reconstituted with 10 mL of the accompanying diluent each vial contains:

Chorionic gonadotropin 5000 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

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

DRUG INTERACTIONS

Tell your doctor if you are using or have recently used any other medicines, including medicines obtained without a prescription.

PRESENTATION

Box containing one vial with 5000 IU of HCG in the form of injectable lyophilic powder.

STORAGE

Before reconstitution:

Store HCG under refrigeration at 2°C to 8°C. Do not freeze. Protect from light. Before opening, the product may be taken out of the refrigerator, without being replaced, for a maximum period of 12 months at room temperature but after this it must be discarded.

After reconstitution:

Reconstituted HCG with preservative may be stored under refrigeration (2°C to 8°C) for up to 4 weeks protected from light.