CHORIONIC GONADOTROPHIN FOR INJECTION I.P.

PUBERGEN® NANO

Highly Purified hCG 500 I.U. For I.M./S.C. Use Only.

Presentation:

Each Box contains 4 ampoules of sterile freeze- dried product contains:

Chorionic Gonadotrophin I.P. 500 I.U.

(As Highly Purified Human Chorionic Gonadotrophin)

Excipients

Mannitol I.P.	12 mg
Potassium Dihydrogen orthophosphate B.P.	0.46 mg
Dipotassium hydrogen orthophosphate B.P.	0.36 mg

Each ampoule of Pubergen Nano is accompanied by a solvent ampoule containing 1 ml sodium chloride injection. The reconstituted solution has a clear appearance.

Pharmacology:

Human Chorionic Gonadotrophin (hCG), a polypeptide produced by the human placenta, is composed of an alpha - & beta – subunit. The alpha – subunit is essentially identical to the alpha- subunits of the Human Pituitary gonadotrophins, Luteinizing Hormone(LH) and Follicle Stimulating hormone as well as the the alpha sub-unit of the Human Thyroid Stimulating hormone(TSH).

Mechanism of Action

Pubergen NANO, is a water soluble glycoprotein derived from natural sources.

In Males:

Prepubertal cryptorchidism not due to anatomic obstruction. In general, HCG is thought to induce testicular descent in situations when descent would have occurred at puberty. HCG thus may help to 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 of 4 and 9.

Low doses of hCG injections are administered to selected cases of hypogonadotropic hypogonadism (hypogonadism secondary to a pituitary deficiency) in males.

Therapy with hCG has also been used for stimulation of spermatogenesis along with HMG and in individuals deficient of endogenous testosterone along with other drugs at the discretion of the Physician

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.

PRECAUTIONS:

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:

hCG can cross react in the radio-immunoassay of gonadotropins, especially lutenising hormone. Each individual laboratory should establish the degree of cross reactivity with their gonadotropin assay.

Carcinogenesis, Mutagenesis, Impairment of Fertility:

Sporadic incidents of testicular cancer have been reported in otherwise healthy normal males, but no correlation could be established that the tumours were caused due to administration of hCG.

Pediatric Use:

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

Adverse Reactions:

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.

Dosage And Administration:

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.

Males

Prepubertal Cryptorchidism not due to natomical obstruction:

500 IP 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 IP Units per injection.

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

Selected cases of hypogonadotropic hypogonadism in males:

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

Induction of Spermatogenesis in selected males

500 to 2,500 IP Units two to three times a week for upto 12 weeks along with FSH / HMG

Testosterone Substitution of Hypogonadal Men

500 to 5000 IP Units two to three times a week for upto 12 – 16 weeks along with other agents or as per the directives of the Physician

Threatened miscarriage and Repeated Loss of Pregnancy (RLP) - (Luteal Phase Defect)

The usual dosage is titrated based on the clinical condition and ranges from 500 IU – 5000 IU.(1 injection on detection of pregnancy, the second on the third day followed by 1 – 2 injections for upto 12 weeks). Though higher doses have been used, it is solely at the discretion of the treating Physician

Luteal Phase Support

With leuprolide trigger on Day 12, Initiate luteal support on Day 14 - 22 (The Dosages are as per available literature and clinical experience. However individual dosages may vary as per patient needs at the discretion of the Physician)

Storage Conditions

Store between 2^{0} C - 8^{0} C. Do not freeze.

How Supplied:

Each box contains 4 ampoules of sterile freeze-dried Chorionic Gonadotrophin (as Highly Purified Human Chorionic Gonadotrophin) along with 1 ml of 0.9% w/v sodium chloride injection as solvent.

References: (Available on Request)

1. **European Journal of Endocrinology 2002**
2. **Journal of Clinical Endocrinology & Metabolism 2005**
3. **Journal of Indian Assoc. Pediatric Surg. Jul – Sep 2005**
4. **Pakistan Journal of Medical Sciences Oct – Dec. 2007 (Part II)**

Manufactured in India by :

SANGYO

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PI/0140(C)/K10

PUBERGEN NANO 4x1 Package Inserter
Job Code PI/0140(C)/K10
Size : 70 x 145 mm