during the first trimester of gestation. PUBERGEN JO should not be administered to a woman who is breast-feeding.

Pregnancy Test: A false result might be obtained if the test is carried out in a patient who has recently undergone (over the last 7 days) or is still having hCG administration.

Adverse Effects :

Adverse effects reported are: headache, irritability, restlessness, depression, fatigue, oedema

Interactions :

No clinically significant drug interactions have been reported.

Over dosage :

may lead to Ovarian hyperstimulation, sudden ovarian enlargement, ascites with or without pain, and/or pleural effusion.

Pharmaceutical Precautions :

Store between 2°C - 8°C.

When reconstituted, the solution should be used immediately.

Presentation:

Each box contains 1 ampoule of of sterile freeze-dried Chorionic Gonadotrophin (As Highly Purified Human Chorionic Gonadotrophin) along with1ml of 0.9 % (w/v) Sodium Chloride injection as solvent.

Unipack sterile syringe, A 24 G needle has also been provided in this pack for single use.

™ Trade Mark under registration.

MANUFACTURED IN INDIA BY:

SANGYO

A Healthcare Unit of UNI-SANKYO LTD

Gaganpahad, R.R. Dist. - 501 323, A.P., India

PI/0135(A)/K10

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

CHORIONIC GONADOTROPHIN FOR INJECTION I.P.

Pubergen JO 7500 I.U.

For I.M./S.C. Use Only.

(Natural, Highly Purified hCG 7500 IU)

Presentation :

Each ampoule of sterile freeze-dried product contains:

Chorionic Gonadotrophin I.P. 7500 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 JO is accompanied by a solvent ampoule containing 1ml sterile 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 and a beta sub-unit. The alpha sub-unit is essentially identical to the alpha sub-units of the Human Pituitary Gonadotrophins, Luteinising hormone (LH) and Follicle Stimulating Hormone (FSH), as well as the alpha sub-unit of Human Thyroid Stimulating hormone (TSH).

The beta sub-units of these hormones differ in the amino acid sequence.

Mechanism of Action :

PUBERGEN JO is a water soluble glycoprotein derived from natural sources. Its action is predominantly luteinising. The action of human chorionic gonadotrophin (hCG) is virtually identical to that of

pituitary Luteinising Hormone (LH). It may also have a small amount of Follicle Stimulating Hormone (FSH) activity. However, it is not considered significant enough to produce an FSH effect.

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.

Pharmacokinetics :

Time to peak effect:

Ovulation usually occurs within 12-36 hours after the preovulatory surge of LH or administration of exogenous hCG used for ovulation induction.

Excretion :

The metabolic clearance rate of hCG has been measured in normal men and regularly cycling women following the administration of PUBERGEN JO. It was found to be 1.6 ml / minute in men and 1.9 ml / minute in women. These volumes are approximately 12 to 25 times lower than the metabolic clearance rate of Luteinising Hormone (LH).

Indications :

Anovulatory infertility:

Infertile females following a treatment regimen with Human menotrophins, Follicle stimulating Hormone or Clomifene.

Dosage and Administration :

PUBERGEN JO is given by intramuscular (24G needle) or subcutaneous route (26G needle). The injection should be reconstituted with the solvent provided, immediately prior to use.

Anovulatory infertility: 7500 IU PUBERGEN JO is given I.M. or S.C. in mid-cycle or at the discretion of the Physician, following treatment with Urofollitrophin or Menotrophin or Clomifene Citrate.

Contraindications :

Pituitary or ovarian tumour, prostatic carcinoma or androgen dependent neoplasm, endocrine disorders, (e.g. hypothyroidism, adrenocortical deficiency or hyperprolactinaemia) in females

Primary ovarian failure (e.g. ovarian dysgenesis, absent uterus, premature menopause) tubal occlusion unless the patient is undergoing superovulation for in-vitro fertilisation.

Active thrombophlebitis.

Prior allergy to PUBERGEN JO.

Warnings and Precautions :

The ovarian hyperstimulation syndrome is generally categorised as:

Mild and Moderate :

Symptoms: abdominal distension, nausea, vomiting, occasional diarrhoea, ovaries enlarged to about 5 to 12cm 3-6 days after hCG administration.

Therapy: rest, close observation.

Pelvic examination of enlarged ovaries should be gentle, in order to avoid rupture of ovarian cysts. Symptoms subside spontaneously over 2-3 weeks.

Severe :

Symptoms: pronounced abdominal distension, ascites with or without pleural effusion, enlarged ovaries (>12cm), decreased blood volume, sometimes cardiovascular shock.

Therapy: hospitalisation, treatment should be conservative focusing on restoring fluid depletion and preventing shock.

The risk of ovarian hyperstimulation syndrome developing in women undergoing superovulation for an assisted conception technique may be lessened if all the follicles are aspirated prior to ovulation.

Pregnancy & Lactation:

Pregnancy, Breast Feeding: Controlled studies in women have not demonstrated any risk for the foetus