PUBERGEN®

Human Chorionic Gonadotrophin for Injection I.P. (H.C.G.)

FOR INTRAMUSCULAR USE ONLY.

DESCRIPTION :

PUBERGEN is a lyophilised preparation of Human Chorionic Gonadotrophin (H.C.G.) I.P., obtained from the urine of pregnant women. It is a white freeze dried, sterile and pyrogen free powder.
The action of **PUBERGEN** (H.C.G.) is virtually identical to that of pituitary LH, although H.C.G. 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 testes to produce androgens and the corpus luteum of the ovary to produce progesterone.

ADMINISTRATION :
PUBERGEN is given by intramuscular injection only. After addition of the solvent provided in the carton, the reconstituted solution should be injected immediately.

INDICATIONS IN FEMALE :
To induce ovulation in cases of anovulatory infertility or impaired follicle ripening and in controlled hyperstimulation regimens to prepare the follicles for puncture and in habitual / recurrent abortion.

INDICATIONS IN MALE :
- Hypogonadotrophic Hypogonadism.
- Delayed puberty associated with insufficient gonadotrophic pituitary function.
- Cryptorchidism, not due to any anatomical obstruction.
- Sterility due to deficient Spermatogenesis.

DOSAGE IN FEMALES :
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. 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.

5000 to 10000 I.U. one injection on 12th day of menstrual cycle or when the Graafian follicle attains a size ≥ 18 mm.

HABITUAL / RECURRENT ABORTIONS :
Once pregnancy is confirmed inject 5000 I.U. of **PUBERGEN** per day on three alternate days. From the 9th day of the first injection 2000 I.U. twice a week, till the 14th week of pregnancy.

DOSAGE IN MALES:
PUBERGEN 5000 I.U. twice weekly for 12 weeks and may have to be continued even upto 1 year to improve semen quality.

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

PRECAUTIONS :
Induction of androgen secretion by Chorionic gonadotrophin may induce precocious puberty in patients for Cryptorchidism. If signs of precocious puberty occur therapy should be discontinued. Since androgen may cause fluid retention, chorionic gonadotrophin should be used with caution in patients with epilepsy, migraine, asthma, cardiac or renal disease.

ADVERSE REACTIONS :
Headache, irritability, edema, restlessness, depression, tiredness, precocious puberty, gynaecomastia and pain a t the site of injection.

CONTRAINDICATIONS :
Precocious puberty, prostatic carcinoma or other androgen dependent neoplasia, prior allergic reaction to Chorionic Gonadotrophin.

WARNING :
H.C.G. should be used by physicians experienced with infertility problems. The principal reactions during the use are :

1. Ovarian enlargement, ascites, with or without pain and/ or pleural effusion.
2. Rupture of ovarian cysts with resultant haemoperitoneum.
3. Multiple births.
4. Arterial thromboembolism.
5. Ovarian hyper stimulation syndrome.

PRESENTATION :
PUBERGEN 1000 I.U.: Box containing 1 ampoule of H.C.G. & 1 ampoule solvent .
PUBERGEN 2000 I.U.: Box containing 1 ampoule of H.C.G. & 1 ampoule solvent.
PUBERGEN 5000 I.U.: Box containing 1 ampoule of H.C.G. & 1 ampoule solvent .
PUBERGEN 10000 I.U. : Box containing 1 ampoule of H.C.G. & 1 ampoule solvent.
With 1 ml Solvent (Sterile Sodium Chloride injection I.P. 0.9% w/v).

STORAGE:
Store below 20°C.

® - Regd. Trade mark

Manufactured in India by:
SANGYO
A Healthcare Unit of UNI-SANKYO LTD
Gaganpahad, R.R. Dist. - 501 323, A.P., India

PI/0119 (B)/K10

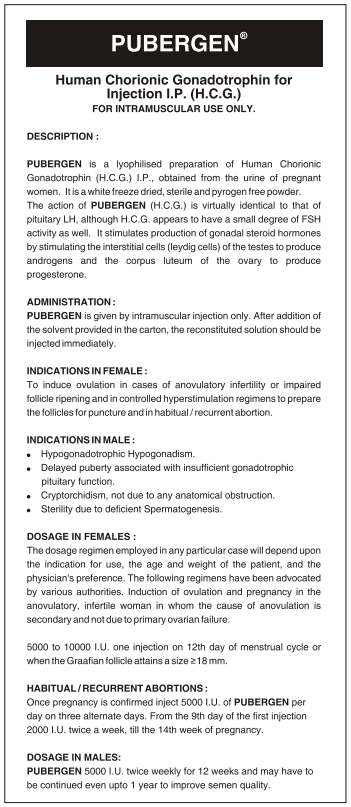
size : 62 mm (w) x 145 mm (h)
Job code : PI/0119 (B)/K10

Refer SOP No.: QA-SOP-017

Annexure III

Packing Material Art Work

Product Name: PUBERGEN
Component Name: INSERT
Component/Item Code: PI/0119(B)/K10



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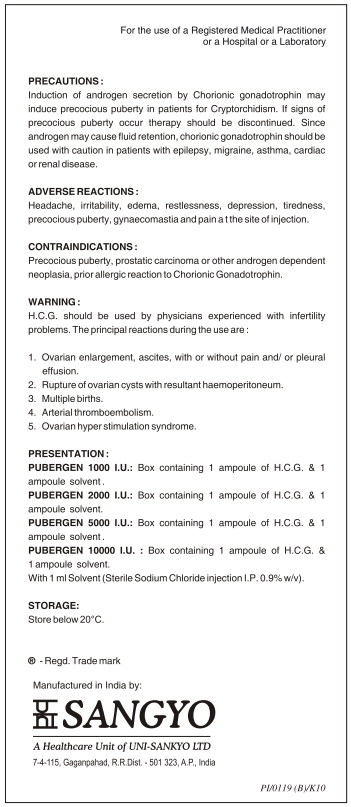

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PI/0119 (B)/K10

SANKYO **UNI-SANKYO LTD.,**

Market: Domestic ☐ / Export ☐
Details of change :New ☐ / Revised ☐
CD given to commercial Dept. by/on:
Cd received by commercial Dept. By/on:
Remarks

Component Color Scheme : ■ C 0 M 0 Y0 K 100 C0 M 0 Y 0 K 0 C0 M0Y0 K0

Art work checked and Approved by/on			
Q.C.	Q.A.	Prod.	Marketing

Art work job code : PI/0119(B)/K10
Dimensions : 62X145 mm
Specifications:
Font : Arial Font Size : 5

Commercial Dept.

Printer Name:

☐ Colour copy of art work enclosed with CD

Printer received CD with colour copy of art work by/on: