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

20002664-01

Chorionic Gonadotrophin For Injection IP 5000 /10000 IU

HCGCAN

5000/10000 IU

Highly Purified

Lyophilized

For IM/SC use only

1. GENERIC NAME
Chorionic Gonadotrophin For Injection IP

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Chorionic Gonadotrophin for Injection IP 5000 IU
Each vial of sterile freeze-dried product contains:
Human Chorionic Gonadotrophin IP …….....5000 IU
Mannitol IP ……..q.s.
Potassium Dihydrogen Phosphate BP……..q.s.
Dipotassium Hydrogen Phosphate BP……..q.s.
Reconstitute with 1ml of Sodium Chloride Injection IP (0.9%w/v) provided with this pack.

Chorionic Gonadotrophin For Injection IP 10000 IU
Each vial of sterile freeze-dried product contains:
Human Chorionic Gonadotrophin IP …….....10000 IU
Mannitol IP ……..q.s.
Potassium Dihydrogen Phosphate BP……...q.s.
Dipotassium Hydrogen Phosphate BP……...q.s.
Reconstitute with 1ml of Sodium Chloride Injection IP (0.9%w/v) provided with this pack.

3. DOSAGE FORM AND STRENGTH
Highly Purified, Lyophilized powder for injection, 5000/10000 IU.

4. CLINICAL PARTICULARS
4.1 Therapeutic Indications:
Anovulatory infertility, cryptorchidism, corpus luteum insufficiency, oligospermia, hypogonadotropic hypogonadism, habitual abortion, asthenospermia.

4.2 Posology and Method of Administration:
For Males
Cryptorchildism and Hypogonadotropin Hypogonadism: In the treatment of prepubertal cryptorchidism, doses regimens vary widely, but doses usually range from 500 to 4000 units three times weekly by intra-muscular injections. For male infertility associated with hypogonadotropic hypogonadism, there is considerable venation in the dosage regiment, and doses have varied from 500 to 4000 units two to three times weekly. An agent with follicle-stimulating activity is often added to enable normal spermatogenesis.
Oligospermia and Asthenospermia: 5000 IU of hCG should be administered in combination with 500 IU of Menotropin every day for 90-120 days.
For females Habitual abortion: 5000 IU of hCG should be administered every other day during the 2nd-3rd months of pregnancy and 1000 IU should be continued to be administered for the following 2 months.
Anovulatory Infertility: The ovary should be stimulated by the administration of proper amount of Menotropin/FSH under physicians indication during the period caused by hypopituitarism or decreased ovarian sensitivity to pituitary Gonadotropin. This administration should be continued until estrogen reaches appropriate level. The ovulation should be induced by administering 5000-10,000 IU of hCG on the first day after the last dose of Menotropin/FSH. If necessary, this treatment can be repeated.
Administration: hCG is given by IM/SC use only. After addition of the solvent provided in the carton, the reconstituted solution should be injected immediately.

4.3 Contraindications
In Males and Females
- Hypersensitivity to the active substance or to any of the excipients.
- Known or suspected sex hormone-dependent tumours, such as ovary, breast and uterine carcinoma in female and prostatic or breast carcinoma in the male.

Additionally in Females
- Malformations of the reproductive organ that contraindicate pregnancy.
- Fibroid tumours in the uterus that contraindicate pregnancy.
- Abnormal (not menstrual) vaginal bleeding without a known/diagnosed cause.

4.4 Special Warnings and Precautions for Use:
In Males and Females
Hypersensitivity Reactions: Hypersensitivity reactions, both generalized and local; anaphylaxis; and angioedema have been reported. If a hypersensitivity reaction is suspected, discontinue Chorionic Gonadotrophin Injection and assess for other potential causes for the event.
General: Patients should be evaluated for uncontrolled non-gonadal endocrinopathies (e.g., thyroid, adrenal or pituitary disorders) and appropriate specific treatment given. Chorionic Gonadotrophin Injection should not be used for body weight reduction. HCG has no effect on fat metabolism, fat distribution or appetite.
Additionally in Females
Multi-fetal gestation and birth
In pregnancies occurring after induction of ovulation with gonadotropic preparations, there is an increased risk of a multiple pregnancies.
Ectopic Pregnancy: Infertile women undergoing Assisted Reproductive Technologies (ART) have an increased incidence of ectopic pregnancy. Early ultrasound confirmation that a pregnancy is intrauterine is therefore important.
Pregnancy Loss: Rates of pregnancy loss in women undergoing ART are higher than in the normal population.
Congenital Malformations: The incidence of congenital malformations after ART may be slightly higher than after spontaneous conceptions. This slightly higher incidence is thought to be related to differences in parental characteristics (e.g., maternal age, sperm characteristics) and to the higher incidence of multiple gestations after ART. There are no indications that the use of Gonadotrophins during ART is associated with an increased risk of congenital malformations.
Ovarian Hyperstimulation Syndrome (OHSS): OHSS is a medical event distinct from uncomplicated ovarian enlargement. Clinical signs and symptoms of mild and moderate OHSS are abdominal pain, nausea, diarrhea, mild to moderate enlargement of evades and ovarian cysts. Severe OHSS may be life-threatening. Clinical signs and symptoms of severe OHSS are large ovarian cysts, acute abdominal pain, ascites, pleural effusion, hydrothorax, dyspnea, oliguria, hematological abnormalities and weight gain. In rare instances, venous or arterial thromboembolism may occur in association with OHSS. Transient liver function test abnormalities suggestive of hepatic dysfunction with or without morphologic changes on liver biopsy have also been reported in association with OHSS. OHSS may be caused by administration of human Chorionic Gonadotropin (hCG) and by pregnancy (endogenous hCG). Early OHSS usually occurs within 10 days after hCG administration and may be associated with an excessive ovarian response to gonadotropin stimulation. Late OHSS occurs more than 10 days after hCG administration, as a consequence of the hormonal changes with pregnancy. Because of the risk of developing OHSS, patients should be monitored for at least two weeks after hCG administration. Women with known risk factors for a high ovarian response may be especially prone to the development of OHSS during or following treatment with Chorionic Gonadotrophin Injection. For women having their first cycle of ovarian stimulation, for whom risk factors are only partially known, close observation for early signs and symptoms of OHSS is recommended. To reduce the risk of OHSS, ultrasonographic assessments of follicular development should be performed prior to treatment and at regular intervals during treatment. The concurrent determination of serum estradiol levels may also be useful. In ART, there is an increased risk of OHSS with 18 or more follicles of 11 mm or more in diameter. When them are 30 or more follicles in total, it is advised to withhold hCG administration.
Depending on the ovarian response, the following measures can be considered to reduce the risk of OHSS:
- Withhold further stimulation with a gonadotropin for a maximum of 3 days (coasting);
- Withhold hCG and cancel the treatment cycle;
- Administer a dose lower than 10,000 IU of urinary hCG for triggering final oocyte maturation, e.g. 5,000 IU urinary hCG or 250 micrograms rec-hCG (which is equivalent to approximately 6,500 IU of urinary hCG);
- Cancel the fresh embryo transfer and cryopreserve embryos;
- Avoid administration of hCG for luteal phase support.

Adherence to the recommended Chorionic Gonadotrophin Injection dose and treatment regimen and careful monitoring of ovarian response is important to reduce the risk of OHSS. If OHSS develops, standard and appropriate management of OHSS should be implemented and followed.
Ovarian Torsion: Ovarian torsion has been reported after treatment with gonadotropins, including hCG. Ovarian torsion may be related to other conditions, such as OHSS, pregnancy, previous abdominal surgery, past history of ovarian torsion, and previous or current ovarian cysts. Damage to the ovary due to reduced blood supply can be limited by early diagnosis and immediate detorsion.
Vascular Complications: Thromboembolic events, both in association with and separate from OHSS, have been reported following treatment with gonadotropins, including hCG. Intravascular thrombosis, which may originate in venous or arterial vessels, can result in reduced blood flow to vital organs or the extremities. Women with generally recognized risk factors for thrombosis, such as a personal or family history, severe obesity or thrombophilia, may have an increased risk of venous or arterial thromboembolic events, during or following treatment with gonadotropins. In these women the benefits of IVF treatment need to be weighed against the risks. It should be noted, however, that pregnancy itself also carries an increased risk of thrombosis.
Medical Examinations: For up to 10 days after administration of Chorionic Gonadotrophin Injection, a pregnancy test may give a false-positive result.

Additionally in Males
Antibody Formation: Administration of hCG can provoke the formation of antibodies against hCG. In rare cases, this may result in an ineffective treatment.
Treatment with hCG leads to increased androgen production. Therefore: Patients with latent or overt cardiac failure, renal dysfunction, hypertension, epilepsy or migraine (or a history of these conditions) should be kept under close medical supervision, since aggravation or recurrence may occasionally be induced as a result of increased androgen production.
hCG should be used cautiously in prepubertal boys to avoid premature epiphyseal closure or precocious sexual development. Use should cease immediately in such cases. Skeletal maturation should be monitored regularly. A growth spurt may also be associated with use and this should be kept in mind particularly where epiphyseal growth is still potentially active.
The product should be used with caution in patients with an allergic diathesis. A preliminary skin test may be of assistance in detecting hypersensitivity. This product should only be used under the supervision of a specialist, for the first administration, having available adequate facilities for appropriate laboratory monitoring.
Patients on a Controlled Sodium Diet: This medicinal product contains less than 1mmol sodium (23 mg) per daily dose, i.e. essentially 'sodium-free'.

4.5 Drugs Interactions:
Interactions of Chorionic Gonadotrophin Injection with other medicines have not been investigated; interactions with commonly used medicinal products can therefore not be excluded.
Fertility, Pregnancy and Lactation: Chorionic Gonadotrophin Injection may be used for luteal phase support, but should not be used later on in pregnancy. It must not be used during lactation.

4.6 Effects on Ability to Drive and Use Machines:
As far as known this medicine has no influence on the ability to drive and use machines.

4.7 Undesirable Effects
Immune System Disorders
In rare cases generalized rash or fever may occur.
General Disorders and Administrative Site Conditions: Chorionic Gonadotrophin Injection may cause reactions at the site of Injection, such as bruising, pain, redness, swelling and itching. Occasionally allergic reactions have been reported, mostly manifesting as pain and/or rash at the injection site.
In the Females
Vascular disorders: In rare instances, thromboembolism has been associated with FSH/hCG therapy, usually associated with severe OHSS.
Respiratory, Thoracic and Mediastinal Disorders: Hydrothorax, as a complication of severe OHSS.
Gastrointestinal Disorders: Abdominal pain and gastrointestinal symptoms such as nausea and diarrhea, related to mild OHSS. Ascites, as a complication of severe OHSS.
Reproductive System and Breast Disorders: Unwanted ovarian hyperstimulation, mild or severe OHSS.
Painful breasts, mild to moderate enlargement of ovaries and ovarian cysts related to mild OHSS. Large ovarian cysts (prone to rupture), usually associated with severe OHSS.
Investigations: Weight gain as a characteristic of severe OHSS.

In the Males
Metabolism and Nutrition Disorders
Water and sodium retention is occasionally seen after administration of high dosages; this is regarded as a result of excessive androgen production.
Reproductive system and breast disorders: hCG treatment may sporadically cause gynaecomastia.
Reporting of side effects: If you experience any side-effects, talk to your doctor or pharmacist.

4.8 Overdosage:
The acute toxicity of urinary gonadotropin preparations has been shown to be very low. Nevertheless, there is a possibility that too high a dosage of hCG may lead to OHSS.

5. PHARMACOLOGICAL PROPERTIES
5.1 Mechanism of Action:
hCG stimulates production of gonadal steroid hormones by stimulating the interstitial cells (Leyding cells) of the test is 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.

5.2 Pharmacodynamic Properties:
hCG which has LH activity. LH is indispensable in normal female and male gamete growth and maturation, and gonadal steroid production.
In the Females
hCG is given as a substitute for the endogenous mid-cycle LH surge to induce the final phase of follicular maturation, leading to ovulation. hCG is also given as a substitute for endogenous LH during the luteal phase.
In the Males
hCG is given to stimulate Leydig cells to promote the production of testosterone.

5.3 Pharmacokinetic Properties:
Maximal hCG plasma levels will be reached in males approximately six and sixteen hours after a single IM or SC injection of hCG respectively, and in females after approximately 20 hours. Although high intersubject variability was observed, the difference related to gender after IM injection may be caused by gluteal fat thickness in women which exceeds that in men. hCG is for approximately 80 per cent metabolized, predominantly in the kidneys. IM and SC administration of hCG were found to be bioequivalent regarding the extent of absorption and the apparent elimination half-lives of approximately 33 hours. On basis of the recommended dose regimens and elimination half-life, cumulation is not expected to occur.

6. NONCLINICAL PROPERTIES
6.1 Animal Toxicology or Pharmacology:
hCG was tolerable and did not cause any mortality by single or repeat dose administration.

7. DESCRIPTION
Chorionic Gonadotrophin is a lyophilized preparation of Human Chorionic Gonadotrophin (hCG) IP, obtained from the urine of pregnant women. It is a white freeze dried, sterile and pyrogen free powder. The action of HCG (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 testes to produce androgens and the corpus luteum of the ovary to produce progesterone.

8. PHARMACEUTICAL PARTICULARS
8.1 Incompatibilities:
None known.
8.2 Shelf-life:
Refer product label for expiry date. Do not use after expiry date.
8.3 Packaging information:
This box contains: 1vial of Chorionic Gonadotrophin Injection IP + 1Ampoule of Sodium Chloride Injection IP (0.9% w/v)1ml.
8.4 Storage and Handling Instructions:
Store between 2°C to 8°C. Do not freeze.

9. PATIENT COUNSELLING INFORMATION
Chorionic Gonadotrophin contains human Chorionic Gonadotropin (hCG), a hormone that is used to cause ovulation and to treat infertility in women. hCG is also used in men to treat hypogonadism, a condition in which the body doesn't produce enough testosterone.
You should not use HCG If you are allergic to It, or If you have:
• Early puberty (precocious puberty); or
• A hormone-related cancer (such as prostate cancer).
You also may not be able to use certain brands of HCG if you have:
• An uncontrolled disorder of your thyroid or adrenal gland;
• Abnormal vaginal bleeding that has not been checked by a doctor;
• An ovarian cyst; or
• Cancer or a tumor of the breast, ovary, uterus, prostate, hypothalamus, or pituitary gland.
Tell your doctor if you have ever had:
Heart disease;
Kidney disease;
Problems with your thyroid or adrenal gland;
Epilepsy;
Migraines; or
Asthma.
Possible Side Effects of hCG
Get emergency medical help if you have signs of an allergic reaction: hives; difficult breathing; swelling of your face, lips, tongue, or throat.
Some women using this medicine develop ovarian hyperstimulation syndrome (OHSS), a potentially life-threatening condition. Call your doctor Fight away if you have symptoms of OHSS:
• Severe stomach pain or pelvic pain;
• Rapid weight gain, swelling around your waist, feeling short of breath;
• Severe nausea and vomiting, diarrhea; or
• Little or no urination.
Call your doctor at once if you have:
• Fluid build-up around the lungs or stomach--rapid weight gain, stomach pain and bloating, pain when you breathe, feeling short of breath while lying down, cough with foamy mucus, rapid heartbeats;
• Signs of a blood clot—sudden numbness or weakness on one side of the body, chest pain, problems with vision or speech, pain or swelling in one leg; or
• Early puberty in boys—enlarged testicles and penis, facial hair, a deepened voice.
Common side Effects may include:
• Headache, depression;
• Feeling restless or irritable;
• Swelling;
• Breast tenderness or swelling; or
• Pain where the medicine was injected.
This is not a complete list of side effects and others may occur. Call your doctor for medical advice about side effects.

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