

Directions for use  
Please read carefully!

## Choragon® 5000

### Composition

1 Ampoule with dry substance contains 5000 IU human chorionic gonadotrophin (HCG) as the active ingredient and mannitol as further ingredient.

1 Ampoule with 1ml solvent contains isotonic sodium chloride solution and dilute hydrochloric acid for PH-adjustment.

### Indications

#### *Female:*

- induction of ovulation, e.g. after stimulation of follicle growth.
- maintenance of corpus luteum function in female patients with luteal phase insufficiency.

#### *Male:*

- delayed puberty, hypogonadotrophic hypogonadism.

#### *As a diagnostic agent:*

- in children to differentiate between cryptorchism and anorchism.
- to assess the function of the testes in patients with hypogonadotrophic hypogonadism before a planned long-term stimulation treatment (Leydig-cell function test).

### Contraindications

#### *Female:*

- If ovarian hyperstimulation is present, HCG should not be used to induce ovulation.
- Tumors affected by sexual hormones.
- Ovarian, uterine or mammary carcinoma
- Extrauterine pregnancy in the last 3 months.
- Gynaecological haemorrhage of unknown aetiology.
- Hypersensitivity against chorionic gonadotrophin or any of the excipients of Choragon®.

- Active thromboembolic disease.

#### *Male:*

- Tumors affected by sexual hormones.
- Hypersensitivity against chorionic gonadotrophin or any of the excipients of Choragon®.

- Active thromboembolic disease.

Choragon® must not be administered in case the treatment outcome is unlikely to be favourable, e.g. in case of:

- Primary ovarian failure.
- Malformations of sexual organs incompatible with pregnancy.
- Uterine myoma incompatible with pregnancy.
- Woman after menopause.

Choragon® should not be administered for ovulation induction in woman with ovarian hyperstimulation.

Active ingredient: Chorionic gonadotrophin

### Paediatrics and andrology

Choragon® must not be used in case of sexual hormone-dependent tumors and in case of undescended testicle known to be of organic origin (inguinal hernia, surgery in the inguinal region, ectopic testicle).

### Special warnings and precautions for use

#### *General*

Choragon® is not induced for reduction of the body weight. HCG does not have any influence of the lipometabolism, fat distribution, appetite or sensation of hunger. *Gynaecology*

Before starting treatment, the couple's infertility should be assessed as appropriate and putative contraindications for pregnancy evaluated. In particular, patients should be evaluated for hypothyroidism, adrenocortical deficiency, hyperprolactinemia and pituitary or hypothalamic tumours, and appropriate specific treatment given.

Patients undergoing stimulation of follicular growth may have a higher risk of ovarian hyperstimulation syndrome (OHSS) due to multifollicle development. An ovarian hyperstimulation syndrome can manifest itself as a severe medical event which is marked by ovarian cysts tending to rupture and the occurrence of ascites together with circulatory disorder. Ovarian hyperstimulation syndrome due to an excessive ovarian reaction may be avoided by withholding hCG. In this case, the patients are to be advised to refrain from coitus for at least 4 days or to use appropriate barrier methods. Close monitoring of the estradiol levels and the ovarian reaction by means of sonography before and during the stimulation therapy is recommended for all patients. The risk of multiple pregnancies after assisted reproduction techniques is related to the number of embryos replaced. Patients undergoing an ovulation induction have a higher risk of multiple pregnancy and/or multiple delivery (mostly twins) compared to the normal conception. In order to minimize OHSS and multiple pregnancy, ultrasound examinations and estradiol measurements are recommended.

Adherence to recommended Choragon® dosage, regimen of administration and careful monitoring of therapy will minimise the incidence of ovarian hyperstimulation or multiple pregnancy. The incidence of pregnancy wastage in anovulatory patients and patients undergoing ART is higher than in the normal population, but comparable to the pregnancy wastage rate of women with other fertility disorders.

### Special information for the treatment

For treatment of sterile women, close monitoring is necessary:

Prior to administration of Choragon®, examinations of follicle growth (ultrasound) and the cervix index (over a period of two days until a stimulation effect is achieved) have to be carried out.

When stimulation symptoms appear during treatment, daily ultrasound examinations and estradiol analyses should be carried out (additionally, the ovarian reaction can be measured by the cervix index).

In case of unintentional hyperstimulation, treatment should be stopped.

#### Ovarian hyperstimulation

In case of slight hyperstimulation (level I) with slight enlargement of the ovaries (ovary size 5 - 7 cm), excessive steroid secretion and abdominal pain, no therapy is necessary. However, the patient should be informed and carefully monitored.

In case of medium hyperstimulation (level II) with ovarian cysts (ovary size 8 - 10 cm) together with abdominal symptoms, nausea and vomiting, clinical supervision, symptomatic treatment and perhaps an intravenous volume replacement in case of high hemoglobin concentration is necessary.

In case of serious hyperstimulation (level III) with large ovarian cysts (ovary size above 10 cm), ascites, hydrothorax, enlarged abdomen, abdominal pain, dyspnea, salt retention, hemoglobin concentration, increased blood viscosity and increased platelet aggregation with the danger of thromboembolisms, hospitalisation is imperative.

### Undesirable effects

#### **Gynaecology:**

After use of hCG (urinary or recombinant), the following undesirable effects may occur:

- headache, fatigue
- vomiting, nausea, diarrhoea
- abdominal pain
- depressions, irritability, restlessness
- exanthem, urticaria, Quincke's oedema
- local reactions at the injection site: bruise, pain, redness, swelling, itching
- allergic reactions, fever.

Following a combined HMG/HCG-or clomiphene/HCG- treatment, ovarian hyperstimulation may occur. This may lead to the formation of large ovarian cysts that tend to rupture, ascites, the accumulation of serous water in the chest cavity and thromboembolism. These side-effects may become more severe if the patient becomes pregnant.

### Paediatrics and andrology

Temporary or long-term gynaecomastia due to the estrogen release and/or proliferative change in the prostate.

Acne vulgaris as well as electrolyte and water retention due to stimulation of testosterone secretion.

Increase in size of penis and erections due to increased testosterone secretion caused by induction.

Occasionally, minor emotional changes in boys similar to those at the beginning of puberty may occur which are limited to the course of treatment.

Long-term treatment can lead to the formation of antibodies leading to loss of effectiveness.

### Interaction with other medicaments

Interactions with other products are unknown. If an unintentional hyperstimulation of the ovaries does occur, it has been caused by treatment with HMG or clomiphene.

### Dosage, Method and Duration of

#### **Administration**

Choragon® is to be injected i.m. unless directed otherwise, please dose as follows:

#### *Female:*

To induce 5000 or 10000 I.U. HCG are injected once i.m.

To maintain corpus luteum function, 1500 - 5000 I.U. Choragon® are to be injected i.m. on the 3<sup>rd</sup>, 6<sup>th</sup>, and 9<sup>th</sup> day following ovulation. If desired, Choragon® 1500 can be used.

#### *Male:*

To induce puberty In boys with pubertas tarda: 3000 - 5000 I.U. Choragon® i.m. once a week over a period of 3 months. If desired, Choragon 1500 can be used.

For hypogonadotrophin hypogonadism (together with HMG) 1500 - 6000 I.U. Choragon® i.m. per week. If desired, Choragon® 1500 can be used.

As a diagnostic agent:

For differential diagnosis in boys with undescended testicles and to assess the function of the testes in patients with hypogonadotrophin hypogonadism: a one time injection of 5000 I.U. HCG i.m.

### Storage and shelf life

Choragon® 5000 should not be stored at temperatures above +25°C.

This preparation should not be used after the expiry date.

**Characteristics**

Chorionic gonadotrophic (HCG) is a hormone produced by the human placenta and is obtained from the urine of pregnant women. The production of certain substances (sexual steroids) is stimulated through the administration of HCG in the reproductive organs. This leads to ovulation in woman and extends the lifespan of the corpus luteum.

In boys and men, this increase in sexual steroid (testosterone among others) can be used to treat delayed puberty, undescended testicles or reproductive organ dysfunctions.

**Presentation and pack size**

3 ampoules with 5000 I.U. each as dry substance and

3 ampoules with 1ml solvent each.

**Manufacturer:**

Ferring GmbH

Wittland 11

P.O. Box 21 45

D-24109Kiel

Germany

Telephone: +49 431.5852-0

Telefax: +49 431.5852-35

Telex: 292432 fearz"

**Marketing Authorisation Holder**

Ferring S.p.A.

Via Senigallia18/2,

Milan

Italy

Telephone: +39 02 6400011

Telefax: +39 02 6400055

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**STORE OUT OF THE REACH OF CHILDREN!**

<b>FERRING</b>
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PHARMACEUTICALS
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