



# Pregnyl®

Freeze-dried  
substance + solvent  
for intramuscular use

## Composition

Each ml of the reconstituted solution contains: 500, 1500 or 5000 I.U. of human chorionic gonadotrophin (hCG).

## Characteristics

Pregnyl is a preparation of human chorionic gonadotrophin obtained from the urine of pregnant women. It stimulates the steroidogenesis in the gonads by virtue of a biologic effect similar to that of hLH (human luteinizing hormone, which is the same as interstitial cell stimulating hormone.) In the male it promotes the production of testosterone and in the female the production of estrogens and particularly of progesterone after the ovulation. In certain cases, this preparation is used in combination with menotrophin (e.g. Humegon). Because hCG is of human origin, no antibody formation is to be expected.

## Indications

### In the male

- Hypogonadotrophic hypogonadism;

if the main complaint is sterility (deficient spermatogenesis):

## Dosage

1000–2000 I.U.  
2–3 times per week;

in combination with menotrophin (75 I.U. hFSH + 75 I.U. hLH daily or 2–3 times a week for at least 3 months).

Once achieved, the improvement in spermatogenesis may in some cases be maintained by hCG alone. Also cases of idiopathic dysspermias have shown a positive response to gonadotrophins.

- Delayed puberty associated with insufficient gonadotrophic pituitary function.
- Cryptorchism, not due to an anatomical obstruction.

1500 I.U. 2–3 times a week for at least 6 months.

Under 6 years of age: 500–1000 I.U. twice weekly for 6 weeks.  
Over 6 years of age: 1500 I.U. twice weekly for 6 weeks. If necessary, this treatment can be repeated.

### In the female

- Ovulation induction in infertility due to anovulation or impaired follicle-ripening and
- in controlled hyperstimulation regimens to prepare the follicles for puncture.

Usually, one injection of 5000–10000 I.U. to complete treatment with a menotrophin preparation (e.g. Humegon). Up to three repeat injections of up to 5000 I.U. may be given within the following 9 days to prevent insufficiency of the corpus luteum.

## Administration

After addition of the solvent to the freeze-dried substance, the reconstituted Pregnyl solution should be administered intramuscularly. Since an opened ampoule cannot be resealed in such a way to further guarantee the sterility of the contents, the solution should be used immediately after reconstitution.

## Contraindications

- Known or suspected androgen-dependent tumours, such as prostatic carcinoma or mammary carcinoma in the male.

## Warnings and precautions

Treatment of male patients with hCG leads to increased androgen production.

Therefore:

- hCG should be used cautiously in prepubertal boys to avoid premature epiphyseal closure or precocious sexual development.
- Patients with latent or overt cardiac failure, renal dysfunction, hypertension, epilepsy or migraine (or a history of these conditions) should be monitored, since aggravation or recurrence may occasionally be induced as a result of increased androgen production.

### In the female:

- In patients treated for infertility due to anovulation or impaired follicle-ripening, the prior administration of menotrophin may lead to unwanted hyperstimulation of the ovaries. In such cases hCG must not be administered, since there is a risk of inducing multiple ovulations and the ovarian hyperstimulation syndrome.
- In pregnancies occurring after induction of ovulation with gonadotrophic preparations, there is an increased risk of miscarriage and multiples.

## Adverse reactions

Skin rashes have rarely been reported.

Water and sodium retention is occasionally seen in males after administration of high dosages; this is regarded as a result of excessive androgen production.

## Overdosage

The toxicity of human chorionic gonadotrophin hormone is very low. There are no symptoms of an acute parenteral overdosage known.

## Marketed by:

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