

PACKAGE LEAFLET: INFORMATION FOR THE USER

Pregnyl 1500 I.U

Powder and solvent for solution for injection

(Human Chorionic Gonadotropin)

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

- 1. What Pregnyl is and what it is used for**
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1. What Pregnyl is and what it is used for

Pregnyl belongs to a group of medicines called gonadotrophins (sex hormones). It controls the release of eggs from the ovary in women, and controls production of the male hormone, testosterone in men.

Women

In female infertility it can be used to cause women to ovulate (**Ovulation induction**). Pregnyl is also used along with other fertility drugs, to help produce eggs in medically assisted reproduction programmes. (**IVF treatment**).

Men

In men it is used to help treat **delayed puberty, undescended testes** or oligospermia (**low sperm count**).

Ask your doctor if you are unsure why you have been given Pregnyl.

2. Before you use Pregnyl

Do not use Pregnyl if you:

- are **allergic** (hypersensitive) to Human Chorionic Gonadotropin (HCG) or any of the other ingredients of Pregnyl.
- have **cancer** (especially a hormone-dependent cancer of the breast, ovaries, womb or the testes) or uterus in the female and prostate tumor in males.
- suffer from **malformations of the sexual organs** incompatible with pregnancy
- suffer from **fibroids in the uterus** that are incompatible with pregnancy
- have recently had **unexpected vaginal bleeding**

Do not use Pregnyl if you have any of the conditions listed above. If any of these conditions apply to you, please tell your doctor before starting to use this medicine.

Take special care with Pregnyl

Medicines are not always suitable for everyone

Tell your doctor before you use Pregnyl if you suffer from or have suffered in the past from any of the following conditions

- Men with
 - heart problems
 - kidney problems
 - high blood pressure
 - epilepsy, or
 - migraine
 - a high tendency for allergic reactions (allergic diathesis)
- abnormalities of the **sexual organs**. Before treatment with Pregnyl your doctor should have checked that your sexual organs are normal.
- in women patients your doctor should have checked how your **ovaries** are working before starting treatment with Pregnyl. Extra supervision may be necessary in some cases.

Pregnyl should be used carefully when treating **boys who have not reached puberty**. This is because it can cause early sexual development and may result in final adult height not being reached.

If you have risk factors for having a **blood clot** (for example being overweight, or if blood clots run in your family), the chance of having a blood clot may be increased during IVF treatment.

Being pregnant increases the chance of having a blood clot.

Fertility treatment

Close supervision of female patients undergoing fertility treatment is extremely important to avoid the rare complication of **hyperstimulation of the ovaries**. The side effect may be felt as pain in the stomach.

→ If you are troubled with stomach pains, **contact your doctor straight away**.

This warning is particularly important with respect to patients with polycystic ovarian disease. Regular monitoring of the response to gonadotropin-treatment helps your doctor to prevent excessive ovarian stimulation. There are no indications that use of Pregnyl during IVF increases the risk of birth defects in your child.

Pregnyl has no effect on **fat metabolism, fat distribution** or **appetite**.

The presence of a **thyroid, adrenal** or **pituitary** illness which is not being treated should be ruled out before using Pregnyl.

Taking other medicines

Some medicines can affect the way Pregnyl works, or Pregnyl may affect how other medicines work.

→ **Tell your doctor or pharmacist** if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy

If treatment with Pregnyl results in pregnancy, there is an increased chance of having twins or multiple births.

Multiple pregnancies carry an increased risk for both the mother and her babies around the time of birth. There is also an increased chance of a miscarriage, or a pregnancy outside the womb (an ectopic pregnancy).

Pregnyl may be used for luteal phase support but should not be used later during pregnancy.

Ask your doctor or pharmacist for advice before taking any medicine.

Breast-feeding

Pregnyl must not be used during lactation.

Driving and using machines

As far is known, Pregnyl has no effect on alertness and concentration.

Important information about some of the ingredients of Pregnyl

This medicinal product contains less than 1 mmol sodium (23 mg) per daily dose, i.e. essentially 'sodium-free'.

3. How to use Pregnyl

Always use Pregnyl exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. Your doctor will decide on the dose of Pregnyl to be given.

In **female patients** one injection is usually given for ovulation induction and a maximum of 3 injections for luteal phase support.

In **male patients** injections are given several times a week for some weeks or months, depending on the problem. Because the development of sperm cells takes about 74 days, treatment should be continued for at least three months before any improvement can be expected.

If you have the impression that the effect of Pregnyl is too strong or too weak, talk to your doctor immediately.

How are the injections given?

Prior to use, the dry powder should be dissolved with the solvent contained in the ampoule with fluid.

This medicine can be injected into muscles (only to be given by a doctor or a nurse) for instance in the buttock, upper leg or upper arm.

If you use more Pregnyl than you should

As your doctor will be keeping a close eye on you it is unlikely you will be given too much, however too high a dose of Pregnyl may cause hyperstimulation of the ovaries. This may be noticed as pain in the abdomen.

If you are troubled by **stomach pains, tell your doctor immediately.**

If you **accidentally use too much** Pregnyl contact your doctor or pharmacist immediately.

The toxicity of Pregnyl is very low.

If you forget to take Pregnyl

If you forget to take a dose **do not take a double dose to make up for a missed dose.**

→ **Contact your doctor.**

If you stop taking Pregnyl

Do not stop taking Pregnyl unless your doctor tells you to. Your doctor will advise you if you need to stop using Pregnyl for any reason.

If you have any further questions on how to take Pregnyl, ask your doctor or pharmacist.

4. Possible side effects

Contact your doctor immediately if you are a woman and experience:

Swelling of abdomen or chest due to fluid retention, weight gain, severe pain in the abdomen, feeling sick (nausea), diarrhoea, or painful breasts, also if it occurs a few days after you receive your last injection, since it could be a sign of unwanted overstimulation of the ovaries (OHSS).

Like all medicines, Pregnyl can cause side effects, although not everybody gets them. The following side effects have been reported:

- Reactions at the site of injection, such as bruising, pain, redness, swelling and itching
- fever.
- rash

If you are a woman:

- Ovarian hyperstimulation syndrome (swelling of abdomen or chest due to fluid retention, weight gain)
- pain in the abdomen
- nausea or diarrhoea.
- painful breasts.
- in rare cases blood clots

If you are a man:

- fluid retention
- enlargement of the breast may occur.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Pregnyl

Keep Pregnyl out of the reach and sight of children.

Do not use Pregnyl after the expiry date which is stated on the carton and ampoule label after 'EXP'. The expiry date refers to the last day of that month.

Store at 2°C – 8°C (in a refrigerator). Keep the ampoules in the outer carton in order to protect from light.

Do not use Pregnyl if you notice that the reconstituted solution contains particles or if the solution is not clear.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further Information

What Pregnyl contains

Each ampoule contains 1500 I.U. of the active ingredient Human Chorionic Gonadotropin.

The other ingredients are:

- carmellose sodium,
- mannitol,
- disodium phosphate dihydrate,
- sodium dihydrogen phosphate dihydrate.

The solvent contains sodium chloride (9 mg), water for injections, sodium hydroxide and hydrochloric acid.

What Pregnyl looks like and contents of the pack

Pregnyl comes as 2 ml ampoules of dry white powder with 1 ml ampoule of solvent (sodium chloride solution).

Pregnyl 1500 I.U. is available in a pack of 1 ampoule of powder and solvent. Not all pack sizes may be marketed.

Marketing Authorisation Holder.

N.V. Organon, Kloosterstraat 6, 5349 AB Oss, The Netherlands

Manufacturer.

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