

Package Leaflet: Information for user
Pregnyl® 5000 I.U. powder for solution for injection
(Human Chorionic Gonadotrophin)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What is Pregnyl and what is it used for?
2. When should you not use this medicine or when should you be extra careful with this medicine?
3. How to use this medicine
4. Possible side effects
5. How to store this medicine
6. Contents of the pack and other information

1. What is Pregnyl and what is it 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. When should you not use this medicine or when should you be extra careful with this medicine?

When should you not use this medicine?

- If you are **allergic** (hypersensitive) to human chorionic gonadotrophin (hCG) or any of the other ingredients of this medicine (listed in section 6).
- If you have a **thyroid, adrenal** or **pituitary** illness which is not being treated.
- If you have **cancer**, (especially a hormone-dependent cancer of the breast, ovaries or womb).
- If you have recently had **unexplained vaginal bleeding** which is not related to your menstrual period.

- If you have **fibroids in the womb** or **abnormalities of the reproductive organs** which make a normal pregnancy impossible.
- If you are a man and have, or suspect you have a hormone-related tumour, such as **testicular, prostate or breast cancer**.

When should you be extra careful with this medicine?

Medicines are not always suitable for everyone.

Talk to your doctor before using Pregnyl if you suffer from or have suffered in the past from any of the following conditions:

- abnormalities of the **reproductive organs**. Before treatment with Pregnyl your doctor should have checked that your reproductive 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.
- uncontrolled pituitary gland or hypothalamic problems.
- underactive thyroid gland (hypothyroidism).
- adrenal glands that are not working properly (adrenocortical insufficiency).
- high prolactin levels in the blood (hyperprolactinaemia).
- any other medical conditions (for example, diabetes, heart disease, or any other long-term disease).

Allergic reactions

Allergic reactions, both generalised and local, including swelling of the face, lips, tongue, and/or throat that may cause difficulty in breathing or swallowing (angioedema and anaphylaxis) have been reported. If you have an allergic reaction, stop taking Pregnyl and seek immediate medical assistance (See also section 4. Possible side effects).

Misuse for weight control

Pregnyl must not be used for weight loss. HCG has no effect on fat metabolism (burning fat), distribution of fat or appetite.

For women:

Chance of having ovarian hyperstimulation syndrome (OHSS)

Treatment with gonadotropic hormones like Pregnyl may cause **ovarian hyperstimulation syndrome (OHSS)**. This is a serious medical condition where the ovaries are overly stimulated and the growing follicles become larger than normal. In rare cases, severe OHSS may be life-threatening. Therefore, close supervision by your doctor is very important. To check the effects of treatment, your doctor will do ultrasound scans of your ovaries. Your doctor may also check blood hormone levels (See also section 4. Possible side effects).

OHSS causes fluid to build up suddenly in your stomach and chest areas and can cause blood clots to form. Call your doctor right away if you have:

- severe abdominal swelling and pain in the stomach area (abdomen)
- feeling sick (nausea)
- vomiting
- sudden weight gain due to fluid build-up
- diarrhoea

- decreased urine output
- trouble breathing

Ovarian Torsion

Ovarian torsion is the twisting of an ovary. Twisting of the ovary could cause the blood flow to the ovary to be cut off.

Before starting to use this medicine, it is important to inform your doctor if you:

- have ever had ovarian hyperstimulation syndrome OHSS
- are pregnant or think that you may be pregnant
- have ever had stomach (abdominal) surgery
- have ever had a twisting of an ovary
- have past or current cysts in your ovary or ovaries

Chance of having a blood clot (thrombosis)

Being pregnant increases the chance of having a blood clot.

If you have risks 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 in a blood vessel (thrombosis) may be increased during IVF treatment.

Blood clots can lead to serious medical conditions, such as:

- blockage in your lungs (pulmonary embolus)
- stroke
- heart attack
- reduced blood flow to the vital organs that may result in organ damage
- reduced blood flow (deep vein thrombosis) to your arm or leg that may result in a loss of your arm or leg.

Please discuss this with your doctor, before starting treatment, especially if:

- you already know you have an increased risk of blood clots
- you, or anyone in your immediate family, have ever had a blood clot
- you are severely overweight.

Chance of having multiple births, birth defects, miscarriage or pregnancy complications

If treatment with Pregnyl results in pregnancy, there is an increased chance having twins or multiple births. Multiple pregnancies carry an increased health risk for both the mother and her babies around the time of birth. In women undergoing fertility treatment there is a slightly increased risk of a miscarriage, or a pregnancy outside of the uterus (an ectopic pregnancy). Therefore, your doctor should perform an early ultrasound examination to exclude the possibility of pregnancy outside the uterus.

It is unknown if IVF treatment causes **congenital malformations**, or some cancers of the **sex organs**.

For men:

Talk to your doctor before using Pregnyl if you suffer from or have suffered in the past from any of the following conditions:

- heart problems
- kidney problems
- high blood pressure
- epilepsy

- migraine

Antibody formation

If the treatment with Pregnyl is not working, consult with your doctor who may perform additional tests.

Treatment with Pregnyl (hCG) can cause the body to produce substances that act against hCG (antibodies to hCG). In rare cases this could result in ineffective treatment.

Children and adolescents

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.

Other medicines and Pregnyl

Some medicines can affect the way Pregnyl works, or Pregnyl may affect how other medicines work. For up to ten days after administration, Pregnyl may result in a false-positive pregnancy test. In case of a positive pregnancy test, contact your doctor.

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

3. How to use this medicine

Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

Your doctor will choose the most suitable starting dose for you. The usual starting doses for men and women are as follows:

Women

Patients undergoing ovulation induction:

5,000–10,000 I.U. Pregnyl following treatment with other fertility drugs.

2 to 3 repeat injections of 1,000 to 3,000 I.U. each may be given within the following 9 days.

Patients undergoing IVF treatment:

5,000–10,000 I.U. Pregnyl **30–40 hours** after the last injection of other fertility drugs.

Men

In male patients injections are given 2 to 3 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.

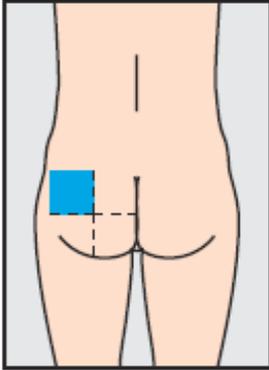
How are the injections given?

The very first injection of Pregnyl should only be given under medical supervision.

Injections may be given slowly **into a muscle** (for instance in the bottom, upper leg or upper arm) or **under the skin** (in the stomach wall, for example).

When given into a muscle the injection should be given by the doctor or nurse. The best site for injection of Pregnyl is the muscle of your bottom. The area shown in blue in the diagram contains a large amount of muscle with few blood vessels or major nerves.

When given under the skin the injection may, in some cases, be given by yourself or your partner. Your doctor will tell you when and how to do this. If you inject yourself with Pregnyl, follow the instructions on this leaflet carefully to give Pregnyl properly and with minimal discomfort.

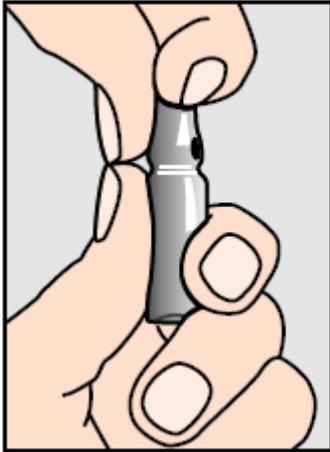


Step 1 - Preparing Pregnyl

Pregnyl comes in two glass ampoules whose contents must be mixed together and used immediately.

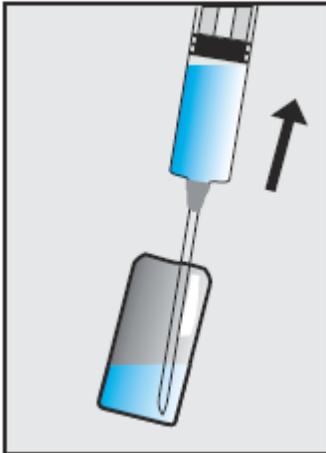
First, break the top off the ampoule with the sodium chloride solution **(a)**.

a.



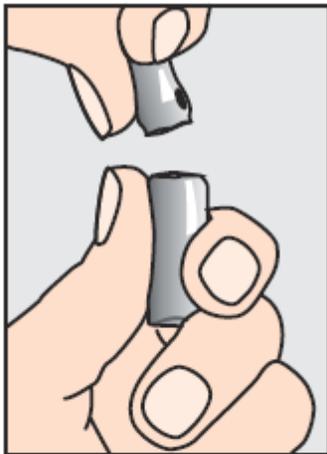
Draw up the liquid through the **larger** needle into the syringe **(b)**.

b.

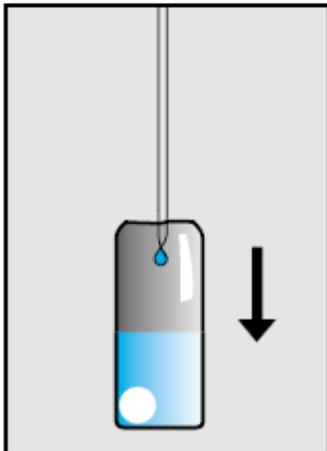


Break open the second ampoule containing the dry white powder (c) and add the sodium chloride solution from the syringe (d).

c.



d.



Do not shake, but **gently swirl** until the solution is clear. The Pregnyl usually dissolves immediately.

If the solution contains particles or does not become clear, do not use it.

Draw the Pregnyl solution up into the empty syringe (**e**), and now **replace** the needle with a **smaller** sterile injection needle (**f**). Finally hold the syringe with the needle pointing upwards and gently tap the side to force any air bubbles up to the top; then squeeze the plunger until all the air has been expelled, and only Pregnyl solution is left in the syringe (**g**).

Step 2 - The injection site

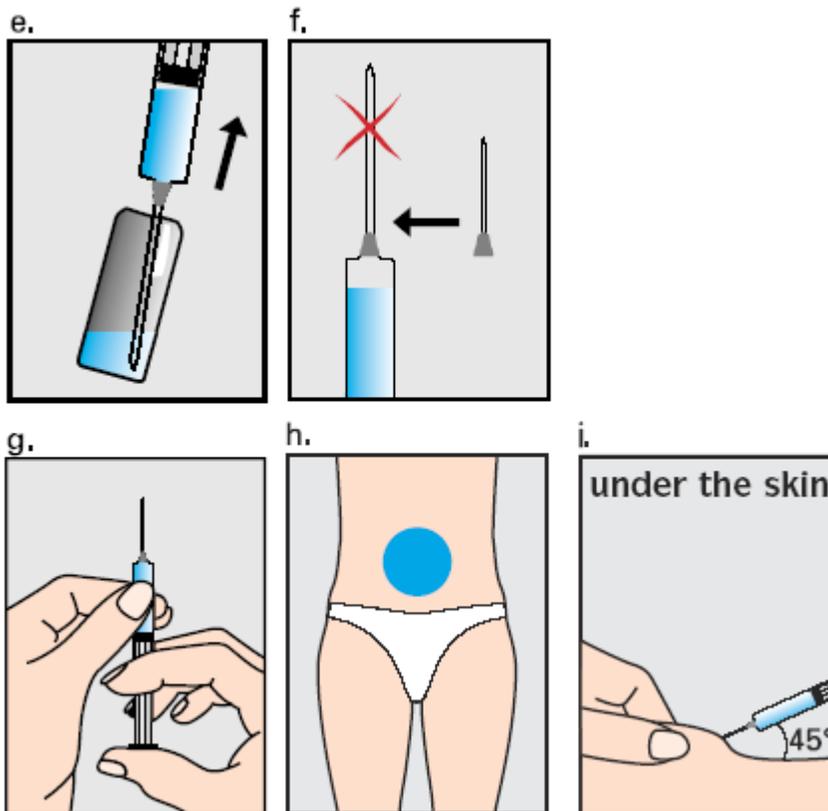
The best site for injection is in the stomach around the middle of the tummy (**h**) where there is a lot of loose skin and layers of fatty tissue. Pinch up a large area of skin between the finger and thumb. You should change the injection site a little each time you inject. It is possible to inject in other areas. Your doctor or nurse will advise you where to inject.

Step 3 - Preparing the area

A few taps at the injection site will stimulate tiny nerve endings and help reduce discomfort when the needle goes in. Hands should be washed and the injection site swabbed with disinfectant (for example chlorohexidine 0.5%) to remove any surface bacteria. Clean about two inches around the point where the needle will go in and let the disinfectant dry for at least one minute before proceeding.

Step 4 - Inserting the needle

The needle should be inserted at the base of the pinched-up skin at an angle of 45° to the skin surface (**i**).



Step 5 - Checking the correct needle position

If the needle position is correct the plunger should be quite difficult to draw back. Any blood sucked back into the syringe means that the needle tip has entered a vein or artery. If this happens pull out the syringe, cover the injection site with a swab containing disinfectant and apply pressure; the site will stop bleeding in a minute or two. **Do not use this solution** but flush it away.

Start again with Step 1 using a new needle and new ampoules of Pregnyl and sodium chloride solution.

Step 6 - Injecting the solution

Depress the syringe plunger slowly and steadily, so the solution is correctly injected and the muscle or skin tissues are not damaged.

Step 7 - Removing the syringe

Pull the syringe out quickly and apply pressure to the injection site with a swab containing disinfectant. A gentle massage of the site - while still maintaining pressure - helps disperse the Pregnyl solution and relieve any discomfort. Any remaining solution should be discarded. Do not mix Pregnyl solution with any other medicines.

Step 8 - Disposing of needles

Replace the needle guard on the syringe to prevent injury.

Carefully dispose of any needles that you use.

You can dispose of needles in a 'sharps bin', or take them to your local pharmacy for disposal. Do not share your needles or syringes.

Always take Pregnyl exactly as your doctor has told you. Check with your doctor or pharmacist if you are still not sure.

If you take 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. See section on Possible side effects below. If you are troubled by **stomach pains, tell your doctor immediately.**

If you **accidentally use too much** Pregnyl contact your doctor at once or go to the nearest hospital casualty department. Always take the labelled medicine package with you, whether there is any Pregnyl left or not.

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

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious side effects: tell a doctor straight away

If you have an allergic reaction to Pregnyl see a doctor straight away

- Pregnyl may cause reactions at the site of injection, such as bruising, pain, redness, swelling and rashes at the injection site.
- more widespread rash and fever may occur (see section 2 “When should you be extra careful with this medicine?”).

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

Severe pain in the abdomen, feeling sick (nausea), diarrhoea, 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).

If you are a woman:

A possible complication of treatment with gonadotropic hormones like Pregnyl is unwanted overstimulation of the ovaries. The chance of having this complication can be reduced by carefully monitoring the number of maturing follicles (small round sacs in your ovaries that contain the eggs). Your doctor will do ultrasound scans of your ovaries to carefully monitor the number of maturing follicles. Your doctor may also check blood hormone levels. The first symptoms of ovarian overstimulation may be noticed as pain in the stomach (abdomen), feeling sick or diarrhoea. Ovarian overstimulation may develop into a medical condition **called ovarian hyperstimulation syndrome (OHSS)**, which can be a serious medical problem. In more severe cases this may lead to enlargement of the ovaries, collection of fluid in the abdomen and/or chest (which may cause sudden weight gain due to fluid build-up) or clots in the blood vessels (See also Section 2 When should you be extra careful with this medicine?).

→ **Contact your doctor without delay** if you have pain in the stomach (abdomen) or any of the other symptoms of ovarian hyperstimulation, even if they occur some days after Pregnyl has been given.

If you are a man:

- fluid may be retained in the tissues, usually marked by swelling of ankles or feet, and occasionally enlargement of the breast may occur. This can be caused by an increased androgen production by treatment with hCG.

→ If any of these signs appear, **tell your doctor immediately**.

Other possible side effects

- acne (in men)
- fluid retention
- headache
- tiredness
- mood changes

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 the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store this medicine

Keep out of the sight and reach of children.

Pregnyl should be stored in a refrigerator (2°C to 8°C).

Do not freeze.

Keep the ampoules in the outer carton in order to protect from light.

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

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

6. Contents of pack and other information

What Pregnyl contains

Each ampoule contains 5000 I.U. of the active ingredient Human Chorionic Gonadotrophin.

The other ingredients are carmellose sodium, mannitol (E421), disodium phosphate (anhydrous), sodium dihydrogen phosphate (anhydrous). The solvent contains sodium chloride (9 mg) and water for injections.

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 5000 I.U. is available in packs of 1, 3 or 10 ampoules of powder and solvent. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Merck Sharp & Dohme Limited,
Hertford Road, Hoddesdon,
Hertfordshire, EN11 9BU, UK

Manufacturer

N.V. Organon, Oss, The Netherlands.

This leaflet was last updated in January 2018.

Other sources of information

In correspondence please quote packing number.

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge: 0800 198 5000 (UK Only)

Please be ready to give the following information:

Product name: Pregnyl 5000 I.U.

Reference Number: PL 00025/0556

This is a service provided by the Royal National Institute of Blind people.

PIL.PRG.5000.17. UK.6115-WS237

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