

Pregnyl® 1500 I.U.
powder for solution for injection
(Human Chorionic Gonadotrophin)

INFORMATION FOR THE USER

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, 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**
- 2. Before you use Pregnyl**
- 3. How to use Pregnyl**
- 4. Possible side effects**
- 5. How to store Pregnyl**
- 6. Further information**

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 Gonadotrophin (HCG) or any of the other ingredients in Pregnyl
- have a **thyroid**, **adrenal** or **pituitary** illness which is not being treated
- have **cancer**, (especially a hormone-dependent cancer of the breast, ovaries or womb)
- have recently had **unexpected vaginal bleeding**
- if you have **fibroids in the womb** or **abnormalities of the sexual organs** which make a normal pregnancy impossible

- are a man and have, or suspect you have a hormone related tumour, such as **testicular, prostate or breast cancer**.

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
- 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 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 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**. This side effect may be felt as pain in the stomach.

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

No one is sure if IVF treatment causes **congenital malformations**, or some cancers of the **sex organs**.

Taking other medicines

Some medicines can affect the way Pregnyl works, or Pregnyl may affect how other medicines work. For the ten days following your Pregnyl injection a pregnancy test may give a false positive result.

→ **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 having twins or multiple births. Multiple pregnancies carry an increased health 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 of the womb (an ectopic pregnancy).

3. How to use Pregnyl

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.

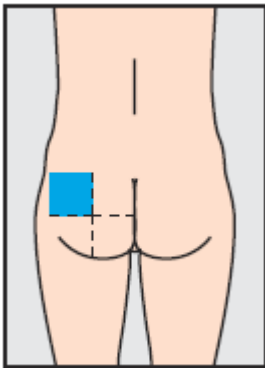
How are the injections given?

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.

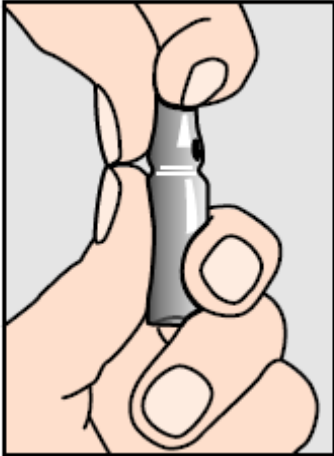


Step 1 - Preparing Pregnyl

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

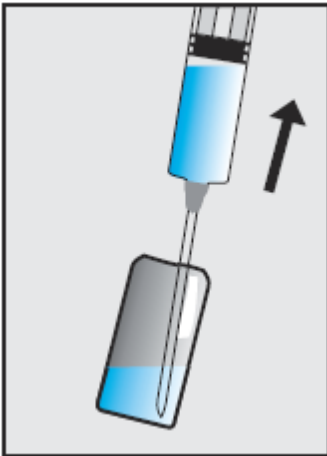
First, break the top off the ampoule with the sodium chloride solution **(a)**.

a.



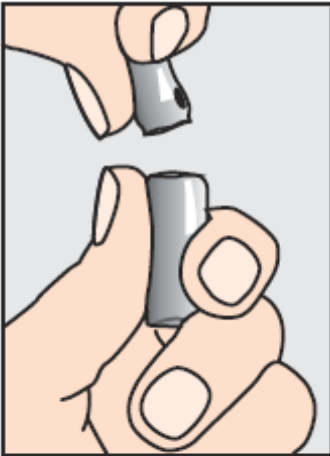
Draw up the liquid through the **larger** needle into the syringe **(b)**.

b.

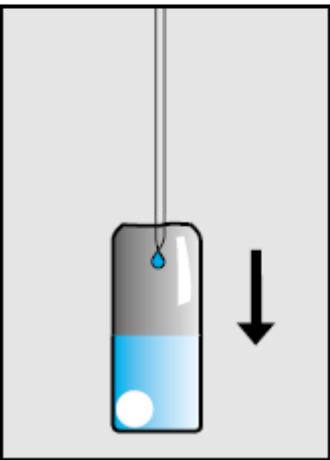


Break open the second ampoule containing the dry white powder **(c)** and add the sodium chloride solution from the syringe **(d)**.

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.

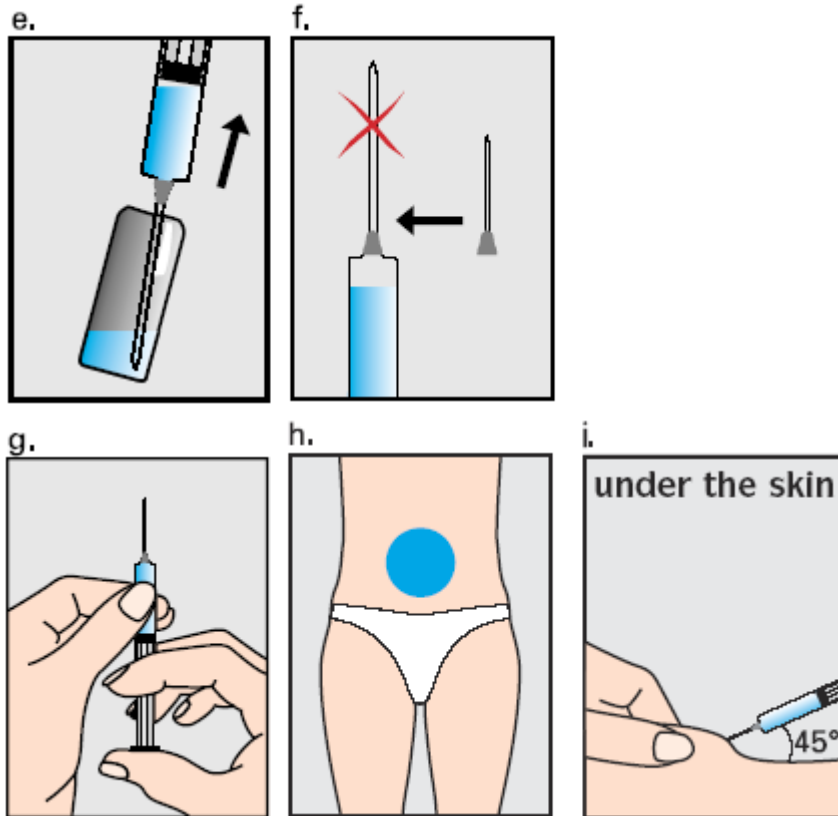
Step 3 - Preparing the area

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, Pregnyl 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.

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:

If your ovaries have been excessively stimulated by an FSH-containing preparation and Pregnyl is given, it may lead to unwanted overstimulation of the ovaries. This condition (also called OHSS) can become very serious, but the risk can be minimised by careful monitoring of egg cell development during treatment. The first symptoms of ovarian overstimulation may be noticed as pain in the stomach (abdomen), feeling sick (nausea) or diarrhoea. In more severe cases

symptoms may include enlargement of the ovaries, accumulation of fluid in the abdomen and/or chest, weight gain and the occurrence of blood clots in the circulation.

→ **Contact your doctor without delay** if you are experiencing significant abdominal pain, also if this occurs some days after the last injection has been given. The following side effects might be the result of OHSS:

- pain in the stomach (abdomen),
- feeling sick (nausea)
- diarrhoea
- bloating
- ovarian cysts or enlargement of the ovaries
- painful breasts
- palpable ovarian cysts
- accumulation of fluid in the abdomen and/ or chest
- blood clots
- ovarian cysts prone to rupture
- weight gain

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

→ If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist. 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**.

5. How to store Pregnyl

Keep out of the reach and sight of children.

Pregnyl should be stored at 2 to 8°C.

Do not freeze.

Keep the ampoules in the outer container to protect from light.

Do not use Pregnyl after the expiry date which is stamped on the pack. 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 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 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 1500 I.U. is available in packs of 1, 3, 5 or 10 ampoules of powder and solvent. Not all pack sizes may be marketed.

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 07/2013.

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 1500 I.U.

Reference Number: PL 00025/0555

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