

Pregnyl®

Human chorionic gonadotrophin (hCG)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Pregnyl.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Pregnyl against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this information with your medicine.

You may wish to read it again.

What Pregnyl is used for

Pregnyl belongs to a group of hormones known as gonadotrophins which play an important part in human fertility and reproduction. It only works if it is injected.

In females:

Pregnyl is used with other medicines to ripen an egg cell in the ovaries and to release the egg (ovulation).

In males:

Pregnyl is used to increase sperm count. It is also used in young boys with un-descended testicles.

Your doctor may have prescribed Pregnyl for another reason.

Pregnyl is not addictive.

A doctor's prescription is required to obtain this medicine.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Before you use Pregnyl

The active ingredient of this preparation is extracted of human urine. Therefore the risk of a transmission of a pathogen (known or unknown) cannot be completely excluded.

When you must not use it

Do not use Pregnyl if:

- you are allergic (hypersensitive) to human gonadotrophins or any of the ingredients listed at the end of the leaflet.
- you have a known or suspected cancer or tumour of the ovary, breast, uterus in the female and prostate or breast carcinoma in the male
- you have malformations of the reproductive organs which make a normal pregnancy not possible
- you have fibroids in the uterus which make a normal pregnancy not possible
- you have heavy or irregular vaginal bleeding, other than menstrual bleeding, without a diagnosed cause.

Do not use Pregnyl if you are breast-feeding.

It is not known whether hCG passes into breast milk.

Do not use Pregnyl after the expiry date printed on the pack.

Do not use Pregnyl if the packaging is torn or shows signs of tampering.

If you are not sure whether you should start using this medicine, talk to your doctor.

Before you are given it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

For men and women:

- Uncontrolled pituitary gland or hypothalamic problems
- An underactive thyroid gland (hypothyroidism)
- Adrenal glands that are not working properly (adrenocortical insufficiency)
- High prolactin levels in the blood (hyperprolactinemia)
- Any other medical conditions (for example, diabetes, heart disease, or any other long-term disease).

If you have any of the conditions listed above, you may not be able to use Pregnyl or you may need a dosage adjustment or special tests during treatment.

Tell your doctor if you have or have had any other medical conditions.

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 Side Effects).

Misuse for weight control

Pregnyl should not be used for body weight reduction. HCG has no effect on fat metabolism, fat distribution or appetite.

If you are a woman:

Chance of having ovarian hyperstimulation syndrome (OHSS)

Treatment with gonadotrophic 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 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 you start to use this medicine, it is important to inform your doctor if you:

- have ever had ovarian hyperstimulation syndrome OHSS

- are pregnant or think 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 multiple births or birth defects

In pregnancies occurring after treatment with gonadotrophic preparations, there is an increased risk of having twins or multiple pregnancies. Multiple pregnancies carry an increased health risk for both the mother and her babies during pregnancy and around the time of birth.

Multiple pregnancies and characteristics of the patients undergoing fertility treatment (e.g. age of the female, sperm characteristics) may be associated with an increased risk of congenital abnormalities.

Chance of having pregnancy complications

In women undergoing fertility treatment there is a slightly increased risk of 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.

Miscarriage

In women undergoing fertility treatment there may be a slightly higher risk of miscarriage.

Chance of having a blood clot (thrombosis)

Treatment with Pregnyl (like pregnancy itself) may increase the risk of the formation of a blood clot in a blood vessel (thrombosis), most often in the veins of the legs or the lungs.

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

- blockage in your lungs (pulmonary embolus)
- stroke

- heart attack
- blood vessel problems (thrombophlebitis)
- reduced blood flow to the vital organs that may result in organ damage
- reduced blood flow to your arm or leg that may result in a loss of your arm or leg.

Tell your doctor, before starting treatment, especially if:

- you already know that 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

If you are a man:

Antibody formation

If the treatment with Pregnyl is not working, consult 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.

Androgen production

Treatment with hCG lead to increased androgen (male sexual hormone) production. Therefore extra supervision by your doctor is necessary

- in the treatment of boys who have not reached puberty. This is because Pregnyl can cause early sexual development and delay growth.
- if you have or have ever had:
 - heart or blood vessel disease
 - kidney disease
 - epilepsy
 - migraine headachesbecause worsening or recurrence may occasionally be induced as a result of increased production of androgens (male sexual hormones).

Taking other medicines

Tell your doctor or pharmacist if you are taking any other

medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

For up to ten days after administration, Pregnyl may result in a false positive pregnancy test.

Ability to drive or operate machinery

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

How Pregnyl is given

Your doctor will decide the dose of Pregnyl.

Pregnyl will be injected into a muscle.

Females may require only one injection.

Males may receive a series of injections 2 to 3 times a week for several weeks or months.

Keep all doctors' appointments so your therapy can be monitored.

If you are given too much

As your treatment will be closely monitored it is unlikely you will be prescribed too large a dose of Pregnyl. However Pregnyl can be associated with the rare condition called Ovarian Hyperstimulation Syndrome (see Side Effects).

While you are given Pregnyl

Things you must do

Tell your doctor immediately if you think you are pregnant or become pregnant while using this medicine.

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Pregnyl.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

Things you must not do

Do not use this medicine to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Side Effects

Tell your doctor as soon as possible if you do not feel well while you are using Pregnyl.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital

- You have pain in the stomach (abdomen) or any of the other symptoms of ovarian hyperstimulation, even if they occur some days after the administration of Pregnyl has been given.
- A possible complication of treatment with gonadotrophic hormones like Pregnyl is unwanted overstimulation of the ovaries. The chance of 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.

- Signs of an allergic reaction such as shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin. These allergic reactions are mostly reported as pain and rash at the injection site.
- Signs of a blood clot such as pain, warmth, redness, numbness, or tingling in your arm or leg; confusion, extreme dizziness or severe headache. This condition is rare.
- In men, 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.

Tell your doctor if you notice any of the following and they worry you:

- Injection site bruising, pain, redness, swelling and itching
- Skin rash and fever
- Breast tenderness or swelling in women

Tell your doctor if you notice any other side effects.

Other side effects not listed in this leaflet also occur in some people.

After using Pregnyl

Storage

Keep Pregnyl in the original box in a safe place out of reach of children.

Pregnyl must be stored in the dark at 2°C to 8°C (Refrigerate. Do not freeze). Protect from light.

The solution should be used immediately after reconstitution.

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

Disposal

The product is for use in one patient only because it contains no antimicrobial preservative. Discard any residue.

Do not use Pregnyl after the expiry date stated on the label.

Return any unused medicine to your pharmacist.

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Macquarie Park NSW 2113
Australia

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Australian Registration Numbers:

Pregnyl 1500 IU: AUST R 273873

Pregnyl 5000 IU: AUST R 273874

Product Description

What it looks like.

The pack contains clear glass vials with 1500 or 5000 IU of human chorionic gonadotrophin as a dry white powder.

The pack also contains a corresponding number of clear glass vials of clear colourless liquid (solvent) which is used to dissolve the white powder.

Do not use this medicine if the glass vials are broken or damaged or if the powder or liquid is discoloured or not clear.

Ingredients

Active ingredient:

- Human chorionic gonadotrophin

Powder also contains:

- Carmellose sodium
- Monobasic sodium phosphate dihydrate
- Dibasic sodium phosphate dihydrate
- Mannitol

The liquid used to dissolve the powder contains sodium chloride and water for injections.

Supplier

Merck Sharp & Dohme (Australia)
Pty Limited
Level 1, Building A,