PUREGON®

follitropin beta[rch]

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about PUREGON.

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 using PUREGON 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 PUREGON is used for

PUREGON solution for injection contains follitropin beta, a hormone known as follicle stimulating hormone (FSH).

FSH belongs to the group of gonadotrophins, which play an important role in human fertility and reproduction. FSH is needed in women for the growth and development of follicles in the ovaries. Follicles are small round sacs that contain the egg cells.

In men, FSH is needed for the production of sperm.

PUREGON is used to treat infertility in any of the following situations:

Women:

- PUREGON can be used to cause ovulation in women who have not responded to treatment with clomiphene citrate.
- PUREGON can be used to bring about the development of multiple follicles in women undergoing assisted reproduction technologies (ART) such as in vitro fertilisation (IVF).

Men:

PUREGON can be used for the production of sperm in men who are infertile due to a hormonal deficiency.

PUREGON is not addictive.

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

Before you use PUREGON

When you must not use it

Do not use PUREGON if you:

- are allergic (hypersensitive) to follitropin beta or to any of the ingredients in PUREGON listed at the end of this leaflet
- have a tumour of the ovary, breast, uterus, testis, or brain (pituitary gland or hypothalamus)
- are pregnant or think you may be pregnant
- have heavy or irregular vaginal bleeding where the cause is not known
- suffer from primary ovarian failure
- have ovarian cysts or enlarged ovaries not caused by polycystic ovarian disease (PCOD)
- have malformations of the sexual organs which make a normal pregnancy impossible
- have fibroid tumours in the uterus which make a normal pregnancy impossible
- suffer from primary testicular failure.

Take special care with Puregon

Tell your doctor if you:

- have experienced an allergic reaction to neomycin and/or streptomycin (antibiotics) in the past. PUREGON may contain traces of these antibiotics
- 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
- you have uncontrolled pituitary gland or hypothalamic problems
- have an underactive thyroid gland (hypothyroidism)
- have adrenal glands that are not working properly (adrenocortical insufficiency)
- have high prolactin levels in the blood (hyperprolactinemia)
- have been told by a doctor that pregnancy would be dangerous for you
- have any other medical conditions (for example, diabetes, heart disease, or any other long-term disease).

In Women

Close supervision by your doctor is very important. Usually ultrasound scans of the ovaries are regularly made. Your doctor may also check blood hormone levels. The results of these tests allow your doctor to choose the correct dose of PUREGON from day to day. This is very important since too high a dose of FSH may lead to rare but serious complications in which the ovaries are overly stimulated and the growing follicles become larger than normal.

This serious medical condition is called ovarian hyperstimulation syndrome (OHSS).

In rare cases, severe OHSS may be life-threatening. 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
- pain in the stomach (abdomen), even if this occurs dome days after the last injection has been given
- nausea (feeling sick)
- vomiting
- sudden weight gain
- diarrhoea
- decreased urine output
- trouble breathing.

Regular monitoring of the response to FSH-treatment helps to prevent ovarian overstimulation.

Ovarian Torsion

Ovarian torsion has occurred after treatment with gonadotrophins including PUREGON. 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 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

Treatment with PUREGON (like pregnancy itself) may increase the risk of having a blood clot (thrombosis). Thrombosis is the formation of a blood clot in a blood vessel.

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

- blockage in your lungs (pulmonary embolus)
- stroke
- heart attack
- blood vessel problems (thrombophlebitis)
- a lack of blood flow (deep venous thrombosis) 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 thrombosis
- you, or anyone in your immediate family, have ever had a thrombosis
- you are severely overweight.

Ovarian and other reproductive system tumours

There have been reports of ovarian and other reproductive system tumours in women who have had infertility treatment. It is not known if treatment with fertility medicines increases the risk of these tumours in infertile women.

Other medical conditions

You have been told by a doctor that pregnancy would be dangerous for you.

In Men

Elevated FSH blood levels are indicative of testicular damage. PUREGON is usually not as effective in such cases. To monitor your treatment, your doctor may ask you for a semen analysis to be performed 4 to 6 months after the beginning of treatment.

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

Do not use PUREGON after the expiry date printed on the pack has passed.
If it has expired or is damaged, return it to your pharmacist or clinic for disposal.

Talk to your doctor if you are not too sure about using PUREGON.

Before you start to use it

You and your partner's fertility should be assessed to see if PUREGON is appropriate for you.

Tell your doctor if you are breastfeeding or intend to breastfeed.

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

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

- thyroid disorder
- adrenal gland disorder
- ovarian cyst
- cancer or a tumour of the breast, ovary, uterus, prostate, hypothalamus or pituitary gland
- polycystic ovarian disease (irregular or no periods, acne, obesity, excess hair growth)
- unexplained vaginal bleeding.

If you have any of the above conditions, tell your doctor before you start to use PUREGON.

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

Pregnancy:
After treatment with gonadotrophic preparations, there is an increased risk of having multiple pregnancies, even when only one embryo is transferred into the uterus. Multiple pregnancies carry an increased health risk for both the mother and her babies around the time of birth.

Furthermore, multiple pregnancies and characteristics of the patients undergoing fertility treatment (e.g age of the female, sperm characteristics, genetic background of both parents) may be associated with an increased risk of birth defects.

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

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.

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.

How PUREGON is given

The very first injection of PUREGON should be given by a health professional.

PUREGON solution for injection in cartridges has been developed for use in the PUREGON Pen. The separate instructions for using the pen must be followed carefully. Do not use the cartridge if the solution contains particles or if the solution is not clear.

Using the pen, injections just under the skin (in the stomach or thigh) can be given by you or your partner. Your doctor will tell you when and how to do this. When the instructions are followed carefully, PUREGON will be administered properly and with minimal discomfort.

How much to inject

Your doctor will decide on the dose of PUREGON to be given. This dose may be adjusted as your treatment progresses.

There are large differences between women in the response of the ovaries to FSH. This makes it impossible to set a dosage schedule which is suitable for all patients. To find the right dosage, follicle growth is checked by means of ultrasound scanning and measurement of the amount of oestradiol (female sex hormone) in the blood.

The following is a guide to the usual dose:

Women who are not ovulating
Initially, a starting dose is set by your doctor. This dose is continued for at least seven days. If there is no response, the daily dose will be gradually increased until an adequate response is obtained. The daily dose is then maintained until a follicle of adequate size is present.

An hCG injection (to stimulate ovulation) is given after the last PUREGON injection.

Women undergoing assisted reproductive technologies
A starting dose is set by your doctor. This dose is continued for at least the first four days. The dose may be adjusted according to your response. When a sufficient number of follicles of adequate size are present, the final phase of maturation of the follicles is induced by administration of hCG. Oocyte (egg) retrieval is performed 34-35 hours later.

Men
PUREGON is usually prescribed at a dose of 75 IU daily or 2-3 times a week, in combination with another hormone (hCG) for at least 3 months.

If you forget to use PUREGON

If you forget an injection or are not sure what to do, contact your doctor or nurse immediately for advice. Do not double the dose on any day.

If you inject too much

Immediately contact your doctor, or for Australia, the Poisons Information Centre (telephone 13 11 26), or for New Zealand, National Poisons Centre (telephone 0800 POISON or 0800 764 766) for advice.

In females, too high a dose may cause overstimulation of the ovaries (Ovarian Hyperstimulation Syndrome, OHSS) (see Side Effects).

While you are using PUREGON

Things you must do

See your doctor regularly so you can be monitored closely throughout your treatment.

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

If you plan to have surgery, tell your doctor or dentist that you are using PUREGON.

Tell all doctors and dentists who are treating you that you are using PUREGON.

Things you must not do

Be careful driving or operating machinery until you know how PUREGON affects you.

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

Do not stop using PUREGON without telling your doctor.

Do not change the dose unless your doctor tells you to.
Changing your dose without telling your doctor can increase your risk of unwanted side effects or can prevent the drug from working properly.

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 PUREGON. All medicines can have side effects. Sometimes they are serious, most of the time they are not.

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

- Bruising, pain, redness, swelling and itching at the injection site
- Skin rash

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

- 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.

For women

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

- 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.

Common side effects (likely to affect 1 to 10 users in 100):

- Headache
- Injection site reactions (such as bruising, pain, redness, swelling and itching)
- Ovarian hyperstimulation syndrome (OHSS)
- Pelvic pain
- Stomach pain and/or bloating

Uncommon side effects (likely to affect 1 to 10 users in 1,000):

- Ovarian torsion (twisting of the ovary) resulting in extreme lower stomach pain
- Breast complaints (including tenderness)
- Diarrhoea, constipation or stomach discomfort
- Enlargement of the uterus
- Feeling sick
- Hypersensitivity reactions (such as rash, redness, hives and itching)
- Ovarian cysts or enlargement of the ovaries
- Vaginal bleeding

A complication with FSH treatment is unwanted overstimulation of the ovaries.

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 serious medical condition called ovarian hyperstimulation syndrome (OHSS). Signs and symptoms of severe OHSS may include:

- Acute stomach pain, weight gain (due to the accumulation of fluid in the abdomen and/or chest), shortness of breath and passing less urine

- In rare cases blood clots. Signs of a blood clots include pain, warmth, redness, numbness, or tingling in your arm or leg; confusion, extreme dizziness or severe headache.

Tell your doctor immediately or go to the Emergency Department at your nearest hospital if you have stomach pains or any of the other symptoms of ovarian hyperstimulation, even if they develop some days after the last injection has been given.

The following side effects are not considered to be related to the use of PUREGON, but to Assisted Reproductive Technology (ART) or subsequent pregnancy:

- Miscarriage
- Ectopic pregnancy (pregnancy that occurs outside the uterus)
- Multiple pregnancies.

For men

Common side effects (likely to affect 1 to 10 users in 100):

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

- Acne
- Hardening of the injection site
- Headache
- Rash
- Some breast development
- Testicular cyst

Tell your doctor if you notice anything that is making you feel unwell.

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

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After using PUREGON

Storage

1. Store PUREGON in the refrigerator (2°C-8°C). Do not freeze. Use until the expiry date printed on the label.
   OR
2. Store at room temperature (at or below 25°C) for a single period of not more than 3 months. Make a note of when you start storing PUREGON out of the refrigerator.

Storage after first dose:
Once you have started using a cartridge, store below 25°C (do not freeze) for a maximum of 28 days.

Disposal

Do not use PUREGON after the expiry date stated on the label after the term 'Expiry Date'.

Return any unused medicine to your pharmacist.

Ingredients

Active ingredient

Follitropin beta, a hormone known as follicle-stimulating hormone (FSH), at a strength of 833 IU/mL aqueous solution per cartridge.

One cartridge of PUREGON contains the following amounts of PUREGON solution:

- 0.480 mL equal to a net dose of 300 IU
- 0.840 mL equal to a net dose of 600 IU
- 1.230 mL equal to a net dose of 900 IU

Other ingredients

- sucrose
- sodium citrate
- methionine
- polysorbate 20
- benzyl alcohol
- water for injections.

The pH may have been adjusted with sodium hydroxide and/or hydrochloric acid anhydrous.

PUREGON 300 IU, 600 IU and 900 IU is available in packs containing one cartridge.

Supplier

Organon Pharma Pty Ltd
Building A
26 Talavera Road
Macquarie Park, NSW 2113
Australia

Organon New Zealand Limited
PO Box 99 851
Newmarket
Auckland 1149
New Zealand

Australian Registration Numbers:
PUREGON 300 IU: AUST R 76436
PUREGON 600 IU: AUST R 76437
PUREGON 900 IU: AUST R 116843

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