

# PUREGON<sup>®</sup>

follitropin beta [rch]

## New Zealand Consumer Medicine Information

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### What is in this leaflet

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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.**

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### What Puregon is used for

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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.**

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### Before you use Puregon

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#### **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 breast feeding
- 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 fibroids 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.

#### **In Women.**

Close supervision by your doctor is very important. Usually ultrasound scans of the ovaries are regularly made, and blood or urine samples are regularly taken. 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 become overstimulated. This condition is called ovarian hyperstimulation syndrome (OHSS). This may be noticed as pain in the stomach (abdomen), feeling sick or diarrhoea. Regular monitoring of the response to FSH-treatment helps to prevent ovarian overstimulation. So contact your doctor without delay if

you are experiencing significant stomach pain, also if this occurs

some days after the last injection has been given.

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

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

### **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. Such pregnancies carry an increased health risk for both the mother and her babies 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.

Generally in women undergoing fertility treatment there may be a slightly higher risk of miscarriage. Women with damaged fallopian tubes have a slightly increased risk of the fetus growing outside the womb (ectopic pregnancy).

### **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.**

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## **How PUREGON is given**

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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 estradiol (female sex hormone) in blood or urine.

**The following is a guide to the usual dose:**

### **Women who are not ovulating**

The dose usually starts at 75-150 IU daily. The dose is continued for at least 5 to 7 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 Purgeon injection.

### **Women undergoing assisted reproductive technologies**

The dose usually starts at 75 to 300 IU daily. 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 the rare condition called Ovarian Hyperstimulation Syndrome (see Side Effects).

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## **While you are using PUREGON**

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### ***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.**

**Ability to drive and operate machinery.**

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

### ***Things you must not do***

**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.**

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## **Side Effects**

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**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 Accident and Emergency 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 Accident and Emergency 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.
- Ovarian torsion (twisting of the ovary) resulting in extreme lower stomach pain.
- Stomach pain, nausea, vomiting or diarrhoea. These are early warning signs of Ovarian Hyperstimulation Syndrome (OHSS)

Other side effects associated with OHSS are:

- enlargement of ovaries, accumulation of fluid in the stomach and/or chest, weight gain, shortness of breath or urinating less than normal and blood clots.
- breast tenderness, pain and /or swelling (uncommon)

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

- headache
- nausea

## For men

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

- acne
- some breast development

**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.**

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## After using Puregon

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### 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 dihydrate
- methionine
- polysorbate 20
- benzyl alcohol
- water for injection

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  
Level 7, 36 Brandon Street  
Wellington 6011  
Tel: 0800 111 700

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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