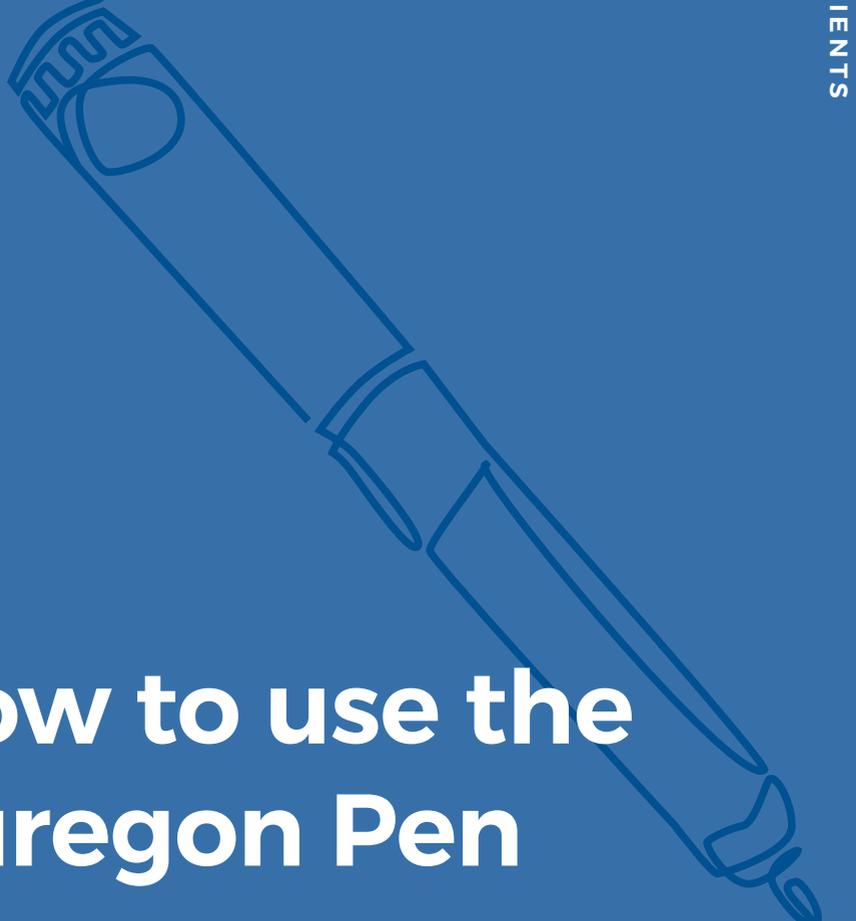




Puregon®

recombinant FSH
follitropin beta

A GUIDE FOR PATIENTS



How to use the Puregon Pen

This booklet is only for patients
prescribed Puregon.

 ORGANON
Fertility

Introduction

As part of your fertility treatment your doctor has prescribed Puregon (recombinant FSH follitropin beta) cartridges for use with the Puregon Pen.

This instruction booklet explains how to administer Puregon with the Puregon Pen device, for educational purposes only. Speak to your doctor or nurse if you have any questions about Puregon or the information provided in this booklet.

Further information about Puregon can also be found in the Consumer Medicine Information (CMI) leaflet which is available online at organon.com/australia or from your local pharmacy or fertility clinic.



What is Puregon used for?¹

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.

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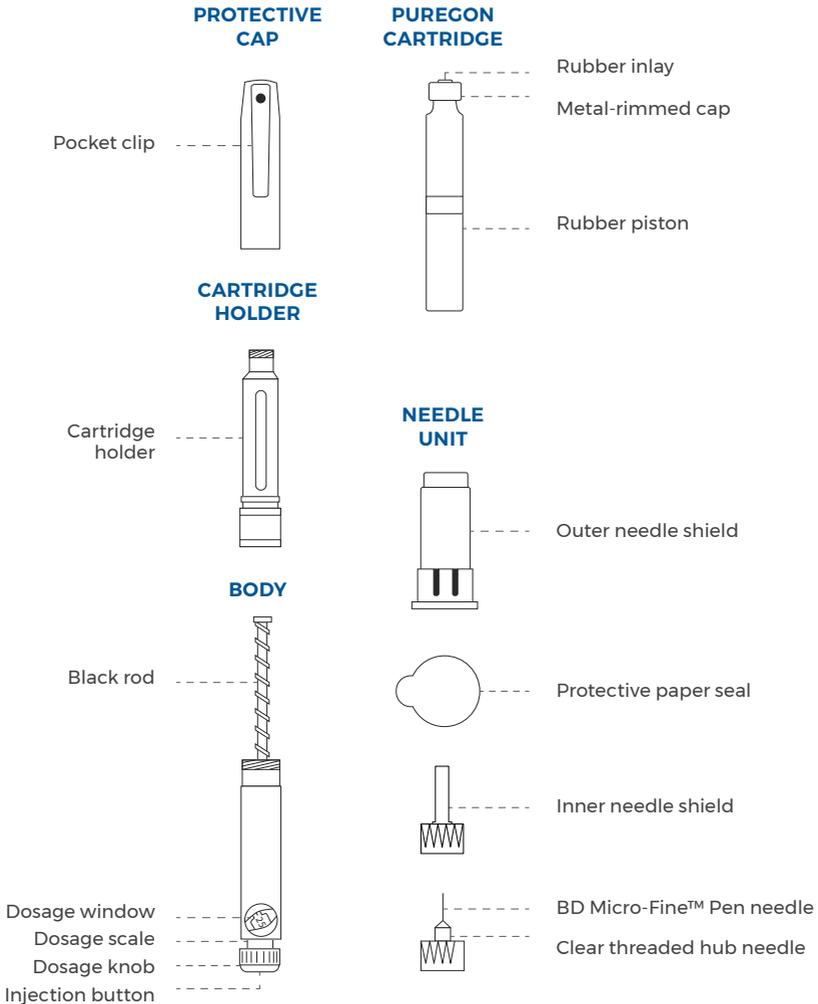
The following contents are covered in this booklet:

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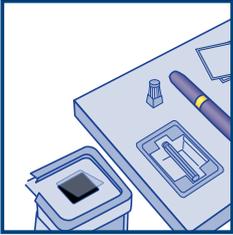


Parts of the Puregon Pen

Your pharmacist will dispense to you a box containing the cartridge and needles but the pen may be given to you by your fertility clinic or the pharmacist separately.



Preparing for your injection



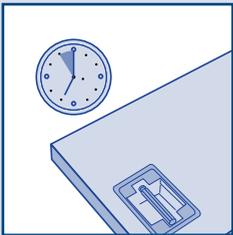
1.1 This is what you will need for each injection:

- Puregon Pen, a Puregon cartridge, the BD Micro-Fine™ Pen Needle provided with the cartridge
- Rubbing alcohol, cotton balls or alcohol pads/swabs, sterile gauze, antibacterial soap
- A sharps disposable container to discard the used needles, cartridges and/or other supplies



1.2 Always wash your hands thoroughly

with antibacterial soap and water before using the Puregon Pen. During your treatment, your doctor will advise you of the best time of the day to inject Puregon. You should try to inject Puregon at the same time of day, every day.



1.3 Take the Puregon cartridge and the Puregon Pen from their storage place.

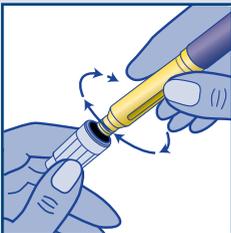
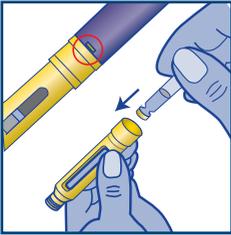
If the cartridge has been stored in the refrigerator, remove it from the refrigerator before you begin your preparations, to bring it up to room temperature (<math><25^{\circ}\text{C}</math>).

Loading and using the Puregon Pen with a new Puregon cartridge



2.1 Loading the Puregon Pen with the Puregon cartridge

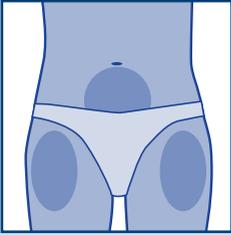
- Remove the protective cap and then unscrew the pen body from the cartridge holder.
- Check that you are using the correct cartridge dose as recommended by your doctor. Puregon cartridges are available as 300 IU (silver cap), 600 IU (gold cap) or 900 IU (blue cap).
- Have a look at the solution within each cartridge to make sure there are no particles present and the solution is clear.
- Clean the rubber inlay at the end of the cartridge with an alcohol swab before placing the cartridge in the cartridge holder with the metal-rimmed cap end first. Then screw on the pen body again.
- The black rod must press against the rubber piston on the cartridge. Make sure no gap is left and the arrow at the end of the cartridge holder points to the middle of the yellow alignment mark at the end of the pen body.



2.2 Attaching the needle

- Before attaching the needle, clean the open end of the cartridge holder with an alcohol pad.
- Remove the paper seal from the outer needle shield and push the end of the cartridge holder firmly into the needle shield. Screw on the needle tightly.
- Place your Puregon Pen with the attached needle aside on a clean, dry surface.

Preparing the injection site



- 3.1** The best place for injection of Puregon is the abdomen, just below the navel. However, other places such as the upper leg can also be used. Your doctor or nurse can show you where. Try to change the exact site of the injection a little each time.



- 3.2** Use the alcohol swab to clean an area of about 4–5 cm around where the needle will enter. Let the alcohol dry (this takes about one minute).

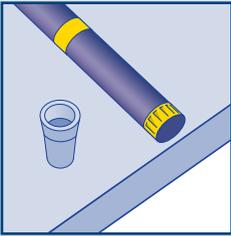


Your doctor will decide on the dose of Puregon to be given. This dose may be adjusted as your treatment progresses

Checking the medication flow and dialling the prescribed dose



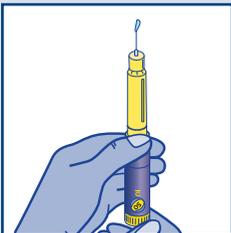
Always check the medication flow by following these steps. This will ensure that the correct dose of Puregon is injected



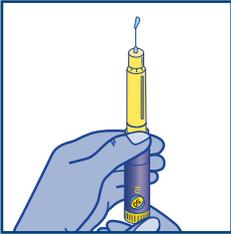
4.1 Remove the outer needle shield and place it with the open end upwards on the table. You will need it later to remove the needle after your injection.



4.2 Holding the pen with the needle pointing upwards, carefully remove the inner needle shield and discard it. Tap the cartridge holder gently with your finger to help air bubbles rise to the top of the needle.



4.3 If you have loaded a new, unused cartridge into the Puregon Pen, dial the dosage knob until you hear one click. With the needle pointing upwards, push in the injection button. Look for a droplet to appear at the tip of the needle. If no droplet appears, repeat this step until a droplet appears. You can now proceed to Step 4.5.



4.4

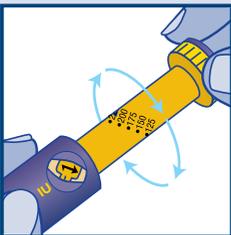
If you have already used the Puregon cartridge to give yourself an injection, simply attach a new needle and look for a droplet to form at the tip of the needle. If a droplet appears, you can proceed directly to dialling your prescribed dose. If no droplet appears, you should follow the instructions in Step 4.3 opposite.



4.5

Dialling the prescribed dose

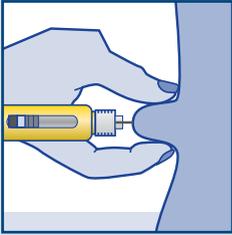
Now dial the knob until the dot beside the correct number on the dosage scale appears in the middle of the dosage window.



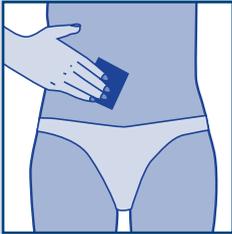
4.6

If you dial past the correct number by mistake, do not try to turn the dosage number backward to fix the mistake. Continue to turn the dosage knob past the 450 IU mark, as far as it will turn. The dosage knob should move freely and no clicks should be heard. Now push the injection button in all the way and redial starting from zero upwards.

Using the Puregon Pen to inject Puregon

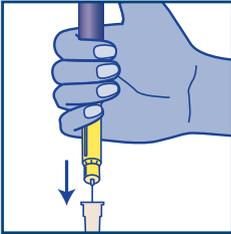


- 5.1** Pinch the skin around the swabbed injection site. With your other hand, insert the entire needle straight into the skin. Press the injection button in all the way until it returns to zero. Wait five seconds before removing the needle from the skin.
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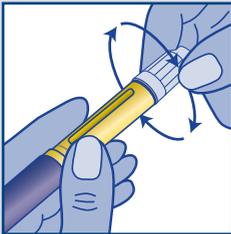
- 5.2** Pull the needle out and cover the injection site with an alcohol swab.

Removing the needle and cartridge after use



6.1 Removing the needle

Place the outer needle shield on the table and insert the needle (attached to the Puregon Pen) into the opening of the shield and push firmly.



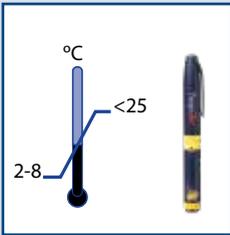
6.2 Hold the shield firmly and unscrew the needle. Deposit the needle properly in the sharps disposal container provided. Put the cap on the Puregon Pen.

6.3 If there is enough Puregon left for further injections, put the pen cap back on the pen body and store your Puregon Pen in a safe place in the refrigerator at 2–8°C (**do not freeze**) or alternatively below 25°C. Never store the Puregon Pen with a needle still attached to it.

6.4 Removing the empty cartridge

Before removing the empty cartridge, make sure that the needle has been removed as described above. Unscrew the pen body from the cartridge holder and remove the empty cartridge. You should place the empty cartridge in the same container that you use for disposal of the used needles. Your doctor or nurse can advise you of how to safely dispose of the container at the end of your treatment. Now you may either put the Puregon Pen back together and store for your next injection, or you can insert a new Puregon cartridge ready for your next injection.

Further information



7.1 Storage¹

Puregon cartridges may be stored in the refrigerator at 2–8°C (**do not freeze**) until the expiration date printed on the carton. Alternatively, you can store Puregon cartridges below 25°C for a single period of not more than 3 months. Do not store the cartridges in the freezer or ice box. Protect from light.

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

Never store the Puregon Pen with a needle still attached.

7.2 If there is not enough Puregon in the cartridge

If you realise before starting the injection, that you do not have enough Puregon in your cartridge, you have two options:

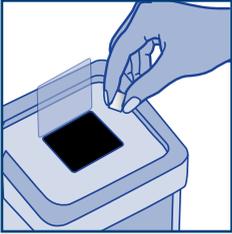
- a) You can dispose of that cartridge, change to a new Puregon cartridge and take your dose or
- b) You should check your treatment diary to confirm how much Puregon is available for injection. You can inject this amount and then take the remainder of your prescribed dose from a new Puregon cartridge as described above



If you have already inserted the needle at the injection site and there is insufficient medication in the cartridge to complete your dose, the injection button will not push in completely and the dosage window will not read zero. The number in the dosage window is the number of units that you will need to complete your dose. If this happens, follow the next steps.

- Wait five seconds before removing the needle from the skin and detach the needle from the Puregon Pen
- You may want to gently apply pressure to the injection site with an alcohol swab
- Write down the position of the dot in the dosage window and the dosage number next to it, at the point where it stopped
- Reset the dosage window to zero by turning the dosage knob past the 450 IU mark and then push the injection button in completely
- Remove the empty cartridge
- Load the Puregon Pen with a new Puregon cartridge, which has been out of the refrigerator for a few minutes
- Attach a new BD Micro-Fine needle
- Prime the needle as described in Step 4.2
- Prepare a different injection site
- Dial the remaining dose you have written down
- Inject the remainder of your prescribed dose
- Remember to wait five seconds before removing the needle from the skin
- Pull the needle out and cover the injection site with a swab

Further information



Always remove the needle from the pen and dispose of it in the sharps disposal container after each injection

Further information about how to use Puregon cartridges with the Puregon Pen can be found in the instructions for use booklet enclosed with your Puregon Pen. Further information about Puregon can also be found in the leaflet enclosed with your cartridge(s). Should you have any further questions, concerns or problems, please contact your clinic or speak to your doctor or fertility nurse.



To view video demonstration online

Scan QR code or visit
puregon.organonconnect.com.au
Password: Support3

Possible side effects¹

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 Puregon, ask your doctor

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 or 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.
- 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

Stomach pain, feeling sick or diarrhoea, are early warning signs of Ovarian Hyperstimulation Syndrome (OHSS). Other side effects associated with OHSS are:

- 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 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 information contained within this booklet is for educational purposes only. Speak to your doctor or nurse if you have any questions about Puregon or the information provided in this booklet.

References: 1. Puregon Consumer Medicine Information (CMI) , January 2021.
2. Puregon Pen Instructions for Use.

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