PUREGON® SOLUTION FOR INJECTION IN CARTRIDGE

Follitropin beta (833IU/ml and 600IU)

What is in this leaflet

What PUREGON is used for

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

Women

- In women who are not ovulating, PUREGON can be used to cause ovulation in women who have not responded to treatment with clomifene citrate.
- In women undergoing assisted reproduction techniques, including *in vitro* fertilisation (IVF) and other methods, PUREGON can be used to bring about the development of multiple follicles.

Men

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

How PUREGON works

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.

Before you use PUREGON

-When you must not use it

Do not use PUREGON if you:

- are allergic (hypersensitive) to follitropin beta or any of the other ingredients of PUREGON (For a full list of ingredients, see "**Product Description**")
- 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 syndrome (PCOS)
- have malformations of the reproductive organs which make a normal pregnancy impossible
- have fibroid tumors in the uterus which make a normal pregnancy impossible
- suffer from primary testicular failure

-Before you start to use it

Please inform your doctor if :

- you have experienced an allergic reaction to neomycin and/or streptomycin (antibiotics) in the past.
- 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 any other medical conditions (for example, diabetes, heart disease, or any other long-term disease).

If you are a woman:

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 notice severe abdominal swelling, pain in the stomach area (abdomen), feeling sick nausea), vomiting, sudden weight gain due to fluid buildup, diarrhoea, decreased urine output or trouble breathing (see also section on **Side Effects**). 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.

Ovarian Torsion. Ovarian torsion has occurred after treatment with gonadotropins 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 to use 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.

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- 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.

After treatment with gonadotrophin preparations, there is an increased chance 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.

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.

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

Other medical conditions
In addition, before starting to use this medicine, tell your doctor if you:
- have been told by a doctor that pregnancy would be dangerous for you.

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

Pregnancy and breast-feeding
Ask your doctor or pharmacist for advice before taking any medicine. You should not use PUREGON if you are already pregnant, or suspect that you might be pregnant.
If you are breastfeeding, tell your doctor before using PUREGON.

-Taking other medicines
If PUREGON is used in combination with clomifene citrate there may be an increased follicular response. If a gonadotropin-releasing hormone (GnRH) agonist (a medicine used to prevent early ovulation) has been given, higher doses of PUREGON may be needed to achieve a response. Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

How to use PUREGON

-How much to use, When to use it and How long to use it
Always use PUREGON exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Dosage in women:
Your doctor will decide on the dose of PUREGON to be given. This dose may be adjusted as your treatment progresses. Further details on the treatment schedule are given below. There are large differences between women in the response of the ovaries to FSH, which 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 the blood.

Women who are not ovulating
Initially, a starting dose of 50IU is set by your doctor. This dose is continued for at least seven days. If there is no ovarian response, the daily dose will then be gradually increased until follicle growth and/or plasma estradiol levels indicate an adequate response. The daily dose is then maintained until a follicle of adequate size is present. Usually, 7 to 14 days of treatment are sufficient. The administration of [PUREGON] is then stopped and ovulation can be induced by administering human chorionic gonadotrophin (hCG).

Medically assisted reproduction progr ams, e.g. IVF
A starting dose is set by your doctor. This dose is continued for at least the first four days. After this, the dose may be adjusted for the individual patient, based upon their ovarian 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.

Dosage in men:
PUREGON is usually prescribed at a dose of 450 IU/week, mostly in 3 dosages of 150 IU, in combination with another hormone (hCG), for at least 3 to 4 months. If you have not responded after this period, your treatment may carry on for at least 18 months.

Method and route of administration
The very first injection of PUREGON should only be given under medical supervision.

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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 abdominal wall, for example) 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.

-If you forget to use it
Do not take a double dose to make up for a forgotten dose.
Do tell your doctor that you missed a dose.

-If you use too much (overdose)
Inform your doctor immediately. Too high a dose may cause overstimulation of the ovaries (OHSS). See section on "**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
- 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 medicine from working properly.
- Do not give your medicine to anyone else, even if they have the same condition as you.

-Things to be careful of
Driving and using machines
No effects on the ability to drive and use machines have been observed.

Side effects
Like all medicines, PUREGON can cause side effects, although not everybody gets them.

Sudden, severe allergic reactions have been reported in users of PUREGON. Reactions may include breathing difficulty, swelling, hives, lightheadedness, fast heartbeat, sweating and loss of consciousness. Frequency cannot be estimated from the available data.

If you are a woman:
A complication with FSH treatment is unwanted overstimulation of the ovaries. Ovarian overstimulation may develop into a medical condition called ovarian hyperstimulation syndrome (OHSS), which can be a serious medical problem. The risk can be reduced by careful monitoring of follicle development during treatment. 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 diarrhea. In more severe cases symptoms may include enlargement of the ovaries, accumulation of fluid in the abdomen and/or chest (which may cause sudden weight gain due to fluid buildup) and the occurrence of blood clots in the circulation. Contact your doctor without delay if you are experiencing any of these symptoms, also if they develop some days after the last injection has been given.

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):
- Breast complaints (including tenderness)
- Diarrhea, 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
- Ovarian torsion (twisting of the ovaries)
- Vaginal bleeding

Rare side effects (likely to affect 1 to 10 users in 10,000):
- Blood clots (this may also occur in the absence of unwanted overstimulation of the ovaries, see also "*Before you start to use it*" in "**Before you use PUREGON**")

Pregnancy outside the uterus (an ectopic pregnancy), miscarriage and multiple pregnancies have also been reported. These side effects are not considered to be related to the use of PUREGON but to Assisted Reproductive Technology (ART) or subsequent pregnancy.

If you are a man:
Common side effects (likely to affect 1 to 10 users in 100)**:**
- Acne
- Hardening of the injection site
- Headache
- Rash
- Some breast enlargement
- Testicular cyst

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.

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You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of PUREGON

-Storage
Keep out of the reach and sight of children.

Storage by the pharmacist
Store at 2ºC – 8°C (in a refrigerator). Do not freeze.

Storage by the patient
You have two options:
1. Store at 2ºC – 8°C (in a refrigerator). Do not freeze.
2. Store at or below 25ºC (at room temperature) for a single period of not more than 3 months.

- Make a note of when you start storing the product out of the refrigerator.
- Keep the cartridge in the outer carton.
- Once the rubber inlay of a cartridge has been pierced by a needle, the product may be used for a maximum of 28 days. Please put the day of first use of the cartridge on the record keeping card as shown in the Instructions For Use of the Puregon Pen.

-Disposal
- Do not use PUREGON after the expiry date which is stated on the label after 'EXP:'.
- Do not use PUREGON if you notice that the solution contains particles or is not clear.
- Discard used needles immediately after injection.
- Discard used cartridges (including the rest volume) after the last injection of the treatment cycle.
- PUREGON cartridges are not designed to allow any other drug to be mixed in the cartridges.
- Empty cartridges must not be refilled.
- 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.

Product Description

-What it looks like
PUREGON solution for injection is a clear, colourless solution. It is supplied in glass cartridges containing a net total dose of 150 IU, 300 IU, 600 IU or 900 IU. It is available in packs of 1 cartridge.

-Ingredients
-Active ingredient:
The active substance is follitropin beta, a hormone known as follicle-stimulating hormone (FSH), at a strength of 833 IU/mL aqueous solution per cartridge.

-Inactive ingredients:
The other ingredients are sucrose, sodium citrate, L-methionine, polysorbate 20 and benzyl alcohol in water for injections. The pH may have been adjusted with sodium hydroxide and/or hydrochloric acid.

-MAL number
Puregon Solution for Injection in Cartridges 833 IU/ml:
MAL13055072ACRSZ

Puregon Solution for Injection in Cartridges 600 IU:
MAL20032269ACRZ

Manufacturer

Puregon Solution for Injection in Cartridges 833 IU:
Vetter Pharma-Fertigung, GmbH & Co. KG, Mooswiesen 2, 88214 Ravensburg, Germany

Puregon Solution for Injection in Cartridges 600 IU:
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Product Registration Holder

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Date of Revision
26/1/2026 (version082023)

Serial Number
NPRA(R3/01)30012024/0290

