PATIENT & CAREGIVER EDUCATION

Follitropin Beta

This information from Lexicomp® explains what you need to know about this medication, including what it’s used for, how to take it, its side effects, and when to call your healthcare provider.

**Brand Names: US**
Follistim AQ

**Brand Names: Canada**
Puregon

**What is this drug used for?**

- It is used to help people get pregnant.
- It is used to help make sperm.

**What do I need to tell my doctor BEFORE I take this drug?**

**For all patients taking this drug:**

- If you are allergic to this drug; any part of this drug; or any other drugs, foods, or substances. Tell your doctor about the allergy and what signs you had.
- If you have any of these health problems: Adrenal gland disease, brain tumor, breast cancer, other cancer where hormones make it grow, pituitary gland disease, or thyroid gland disease.
**Females:**

- If you have any of these health problems: A tumor in your female organs, enlarged ovaries or ovarian cysts, or vaginal bleeding where the cause is not known.
- If your ovaries no longer make eggs (primary ovarian failure).
- If you are not able to get pregnant because of problems with your sex organs.
- If you are pregnant or may be pregnant. This drug is not for use during pregnancy. A pregnancy test will be done to show that you are NOT pregnant before starting this drug.

**Males:**

- If you are not able to make sperm or you have a tumor in your male organs.

This is not a list of all drugs or health problems that interact with this drug.

Tell your doctor and pharmacist about all of your drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe for you to take this drug with all of your drugs and health problems. Do not start, stop, or change the dose of any drug without checking with your doctor.

**What are some things I need to know or do while I take this drug?**

**For all patients taking this drug:**

- Tell all of your health care providers that you take this drug. This includes your doctors, nurses, pharmacists, and dentists.
- Have your blood work and other lab tests checked as you have been told by your doctor.
Females:

- You will need to have ultrasounds done while using this drug. Talk with your doctor.

- This drug may raise the chance of getting pregnant with more than one baby.

- This drug may raise the chance of very bad side effects like enlarged ovaries and ovarian cysts that burst. Rarely, these effects have been deadly. Talk with the doctor.

- If your ovaries get too big, your doctor may tell you that you need to avoid sex. Having sex may cause an ovarian cyst to burst. Talk with your doctor.

- This drug may raise the chance of twisting of the ovaries (ovarian torsion) in people with some health problems. This can cause blood flow to the ovary to be cut off. Talk with the doctor.

- The chance of pregnancy outside the uterus (ectopic pregnancy) may be raised in some people. If you have questions, talk with the doctor.

- Limit working out while undergoing ovarian stimulation. Talk with your doctor.

- The rate of pregnancy loss (miscarriage) is higher when using drugs like this one than in a natural pregnancy. It is not known if these drugs caused this effect. If you have questions, talk with the doctor.

- Rarely, tumors of the ovary have been reported in patients who have had repeated treatments like this one to get pregnant. It is not known if this drug may be the cause. If you have questions, talk with the doctor.

- Tell your doctor if you are breast-feeding. You will need to talk about any risks to your baby.
What are some side effects that I need to call my doctor about right away?

**WARNING/CAUTION:** Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your doctor or get medical help right away if you have any of the following signs or symptoms that may be related to a very bad side effect:

**For all patients taking this drug:**

- Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing, swallowing, or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat.
- Pale skin.
- Severe lung problems have happened with this drug. Rarely, this has been deadly. Call your doctor right away if you have signs of lung problems like shortness of breath or other trouble breathing, cough, or fever.
- Blood clots have happened with this drug. Sometimes, these blood clots have been deadly. Call your doctor right away if you have chest, arm, back, neck, or jaw pain or pressure; coughing up blood; numbness or weakness on 1 side of your body, trouble speaking or thinking, change in balance, or change in eyesight; shortness of breath; or swelling, warmth, or pain in the leg or arm.

**Females:**

- Vaginal bleeding that is not normal.
- Ovarian hyperstimulation syndrome (OHSS) is a severe side effect that may happen in some people who use this drug. Call your doctor right away if you have severe stomach pain or bloating; very upset stomach, throwing up, or diarrhea; a big weight gain; shortness of breath; or change in how much urine is passed.
**Males:**

- Enlarged breasts.

**What are some other side effects of this drug?**

All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects bother you or do not go away:

**For all patients taking this drug:**

- Irritation where the shot is given.
- Upset stomach.
- Pimples (acne).
- Headache.
- Feeling tired or weak.

**Females:**

- Pelvic pain.
- Stomach pain.

These are not all of the side effects that may occur. If you have questions about side effects, call your doctor. Call your doctor for medical advice about side effects.

You may report side effects to your national health agency.

You may report side effects to the FDA at 1-800-332-1088. You may also report side effects at [https://www.fda.gov/medwatch](https://www.fda.gov/medwatch).

**How is this drug best taken?**

Use this drug as ordered by your doctor. Read all information given to you. Follow all instructions closely.
• It is given as a shot.
• If you will be giving yourself the shot, your doctor or nurse will teach you how to give the shot.
• Wash your hands before and after use.
• Move the site where you give this drug as you were told by the doctor.
• If stored in a refrigerator, let this drug come to room temperature before giving a dose.
• Do not use if the solution is cloudy, leaking, or has particles.
• Do not use if solution changes color.
• Do not give into tender, bruised, red, or hard skin.
• This product may make a clicking sound as you prepare the dose. Do not prepare the dose by counting the clicks. Doing so could lead to using the wrong dose.
• Remove all pen needle covers before injecting a dose (there may be 2). If you are not sure what type of pen needle you have or how to use it, talk with the doctor.
• Throw away needles in a needle/sharp disposal box. Do not reuse needles or other items. When the box is full, follow all local rules for getting rid of it. Talk with a doctor or pharmacist if you have any questions.
• Do not share pen or cartridge devices with another person even if the needle has been changed. Sharing these devices may pass infections from one person to another. This includes infections you may not know you have.

What do I do if I miss a dose?

• Call your doctor to find out what to do.
How do I store and/or throw out this drug?

All products:

- Store unopened containers in a refrigerator. Do not freeze.
- If needed, you may store unopened containers at room temperature for up to 3 months. If stored at room temperature and not used within 3 months, throw this drug away.
- Store in the outer carton to protect from light.
- Keep all drugs in a safe place. Keep all drugs out of the reach of children and pets.
- Throw away unused or expired drugs. Do not flush down a toilet or pour down a drain unless you are told to do so. Check with your pharmacist if you have questions about the best way to throw out drugs. There may be drug take-back programs in your area.

Cartridges:

- Once a needle is put into the rubber, store in a refrigerator or at room temperature. Throw away any part not used after 28 days.

General drug facts

- If your symptoms or health problems do not get better or if they become worse, call your doctor.
- Do not share your drugs with others and do not take anyone else’s drugs.
- Some drugs may have another patient information leaflet. If you have any questions about this drug, please talk with your doctor, nurse, pharmacist, or other health care provider.
- Some drugs may have another patient information leaflet. Check with your pharmacist. If you have any questions about this drug, please talk with your doctor, nurse, pharmacist, or other health care provider.
- If you think there has been an overdose, call your poison control center or get medical care right away. Be ready to tell or show what was taken,
how much, and when it happened.

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