

PATIENT INFORMATION LEAFLET

Follistim® (Fol'-lis-tim) AQ (follitropin beta injection)

Single-Use Vial

Read the Patient Information that comes with Follistim® AQ before you start using it and each time you get a refill. There may be new information. This information does not take the place of talking with your healthcare provider about your medical condition or treatment.

What is Follistim AQ?

Follistim AQ is a prescription medicine that contains follicle-stimulating hormone (FSH).

Follistim AQ is used:

In women:

- to help healthy ovaries to develop (mature) and release eggs
- as part of an Assisted Reproductive Technology (ART) program to help the ovaries produce more mature eggs

In men:

- to help bring about the production and development of sperm

Who should not take Follistim AQ?

Do not take Follistim AQ if you are a Woman or Man who:

- is allergic to recombinant human FSH products
- has a high level of FSH in your blood indicating that your ovaries (women only) or testes (men only) may be permanently damaged and do not work at all
- has uncontrolled thyroid, pituitary, or adrenal gland problems
- is allergic to streptomycin or neomycin (types of antibiotics)
- has a tumor of the hypothalamus, pituitary gland, breast, uterus (women only), ovary (women only), or testis (men only)

Do not take Follistim AQ if you are a Woman who:

- is pregnant or think you may be pregnant
- has heavy or irregular vaginal bleeding and the cause is not known
- has ovarian cysts or enlarged ovaries, not due to polycystic ovary syndrome (PCOS)

Talk to your healthcare provider before taking this medicine if you have any of the conditions listed above.

What should I tell my healthcare provider before taking Follistim AQ?

Before you take Follistim AQ, tell your healthcare provider if you:

- have an increased risk of blood clots (thrombosis)
- have ever had a blood clot (thrombosis), or anyone in your immediate family has ever had a blood clot (thrombosis)
- had stomach (abdominal) surgery
- had twisting of your ovary (ovarian torsion)
- had or have a cyst in your ovary
- have polycystic ovary disease
- have any other medical conditions
- are breastfeeding or plan to breastfeed. It is not known if Follistim AQ passes into your breast milk. You and your healthcare provider should decide if you will take Follistim AQ or breastfeed. You should not do both.

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

Know the medicines you take. Keep a list of them and show your healthcare provider and pharmacist when you get a new medicine.

How should I use Follistim AQ?

- Be sure that you read, understand, and follow the "Patient Instructions for Use" that come with Follistim AQ.
- Use Follistim AQ exactly as your healthcare provider tells you to.
- Your healthcare provider will tell you how much Follistim AQ to use, how to inject it, and how often it should be injected.
- Do not inject Follistim AQ at home until your healthcare provider has taught you the right way.
- Do not mix Follistim AQ with any other medicines in the same vial or in the same syringe.
- Do not change your dose of Follistim AQ unless your healthcare provider tells you to.
- **Call your healthcare provider immediately** if you use too much Follistim AQ.
- If you miss or forget to take a dose, do not double your next dose. Ask your healthcare provider for instructions.
- Your healthcare provider will do blood and urine hormone tests while you are taking Follistim AQ. Make sure you follow-up with your healthcare provider to have your blood and urine tested when told to do so.

Women:

- Your healthcare provider may do ultrasound scans of your ovaries. Make sure you follow-up with your healthcare provider to have your ultrasound scans.

Men:

- Your healthcare provider may test your semen while you are taking Follistim AQ. Make sure you follow-up with your healthcare provider to give a semen sample for testing.

What are the possible side effects of Follistim AQ?**Follistim AQ may cause serious side effects.****Serious side effects in women include:**

- **Ovarian enlargement**
- **Ovarian hyperstimulation syndrome (OHSS).** OHSS is a serious medical problem that can happen when the ovaries are over stimulated. In rare cases it has caused death. OHSS causes fluid to build up suddenly in your stomach and chest areas and can cause blood clots to form. Call your healthcare provider right away if you have:
 - pain in your lower stomach area
 - nausea
 - vomiting
 - weight gain
 - diarrhea
 - decreased urine output
 - trouble breathing
- **Lung problems.** Follistim AQ can cause you to have fluid in your lungs (atelectasis) and trouble breathing (acute respiratory distress syndrome).
- **Blood clots.** Follistim AQ may increase your chance of having blood clots in your blood vessels. Blood clots can cause:
 - blood vessel problems (thrombophlebitis)
 - stroke
 - loss of your arm or leg
 - blood clot in your lungs (pulmonary embolus)
 - heart attack
- **Ovarian torsion.** Follistim AQ may increase the chance of twisting of the ovaries in women with certain conditions such as OHSS, pregnancy and previous abdominal surgery. Twisting of the ovary could cause the blood flow to the ovary to be cut off.
- **Pregnancy and birth of multiple babies.** Having a pregnancy with more than one baby at a time increases the health risk for you and your babies. Discuss your chances of multiple births with your healthcare provider.
- **Birth defects.** A woman's age, certain sperm problems, genetic background of both parents and a pregnancy with multiple babies can increase the chance that your baby might have birth defects.
- **Ectopic pregnancy (pregnancy outside of the womb).** The chance of a pregnancy outside of the womb is increased in women with damaged fallopian tubes.
- **Miscarriage.** The chance of loss of an early pregnancy may be increased in women who have difficulty with becoming pregnant at all.

The most common side effects of Follistim AQ include:**In women:**

- cyst in the ovary
- stomach pain

In men:

- headache
- pain at the injection site
- bruising, swelling or redness at the injection site
- breast enlargement
- acne

These are not all the possible side effects of Follistim AQ. For more information, ask your healthcare provider or pharmacist.

Call your healthcare provider immediately if you get worsening or strong abdominal pain. Also, call your healthcare provider immediately if this happens some days after the last injection has been given.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store Follistim AQ?

- Store Follistim AQ in the refrigerator between 2° - 8°C (36° - 46°F) until the expiration date.
- Follistim AQ can be stored at or below 25°C (77°F) for 3 months or until the expiration date, whichever comes first.

- Keep Follistim AQ away from light.
- Do not freeze.

Keep Follistim AQ and all medicines out of the reach of children.

General information about Follistim AQ

Medicines are sometimes prescribed for purposes other than those listed in the Patient Information leaflet. Do not use Follistim AQ for a condition for which it was not prescribed. Do not give Follistim AQ to other people, even if they have the same condition that you have. It may harm them.

This Patient Information leaflet summarizes the most important information about Follistim AQ. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for more information about Follistim AQ that is written for healthcare professionals.

For more information, go to **www.follistim.com** or call 1-866-836-5633.

What are the ingredients in Follistim AQ?

Active ingredient: follitropin beta

Inactive ingredients: sucrose, sodium citrate, L-methionine, polysorbate 20, water for injection, hydrochloric acid, and/or sodium hydroxide.

Manufactured for: Merck Sharp & Dohme Corp., a subsidiary of
 **MERCK & CO., INC.**, Whitehouse Station, NJ 08889, USA

Manufactured by: N.V. Organon, Oss, The Netherlands, a subsidiary of
Merck & Co., Inc., Whitehouse Station, NJ 08889, USA

For patent information: www.merck.com/product/patent/home.html

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PATIENT INSTRUCTIONS FOR USE

Follistim® (Fol'-lis-tim) AQ

(follitropin beta injection)

Single-Use Vial

Read the Patient Instructions for Use that comes with Follistim® AQ before you start using it and each time you get a refill. There may be new information. This information does not take the place of talking with your healthcare provider about your medical condition or treatment.

A. Getting Ready

- Remove the vial from the refrigerator.
- Check the liquid in the vial. It should appear clear and colorless. If the solution is not clear and colorless or has particles in it, **do not use it.**
- **Gather the supplies you will need for your injection. You will need:**
 - a clean dry surface
 - alcohol
 - cotton balls or alcohol pads
 - sterile gauze
 - a puncture-proof container to throw away the used syringe and needle
- Wash your hands and dry them.

B. Preparing your Follistim AQ Injection

- Flip off the protective cap on the top of the vial. **Do not** remove the rubber stopper. Wipe the top of the rubber stopper with an alcohol wipe.
- Use a syringe and needle that has been recommended by your healthcare provider, attach a needle to the syringe.

C. Draw up your Dose

- Carefully remove the needle cover (cap) from the needle (See Figure 1).

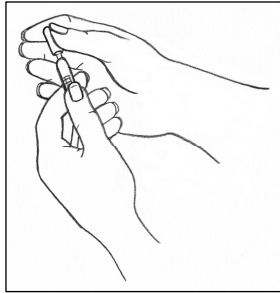


Figure 1

- Pull back on the plunger to draw the amount of air into the syringe equal to the dose needed.
- With the vial on a flat work surface, insert the needle straight down through the rubber stopper of the Follistim AQ vial.
- Push the plunger of the syringe down to inject the air from the syringe into the vial of Follistim AQ. The air injected into the vial will allow Follistim AQ to be easily withdrawn into the syringe.
- Keep the needle inside the vial. Turn the vial and syringe upside down. Be sure that the tip of the Follistim AQ needle is in the liquid. Slowly pull back on the plunger to fill the syringe with Follistim AQ liquid to the number (mL or cc) that matches the dose your healthcare provider prescribed (See Figure 2).

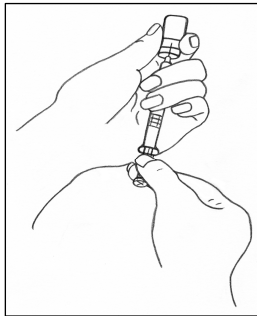


Figure 2

D. Remove the Air

- Hold the syringe with the needle pointed up. Check for air bubbles in the syringe. A small amount of air will not hurt you. If you see large air bubbles, gently tap the side of the syringe with your finger until the air bubbles rise to the top of the syringe.
- Slowly push the plunger to force the air bubbles out of the syringe. You will see a drop of liquid on the tip of the needle (See Figure 3).

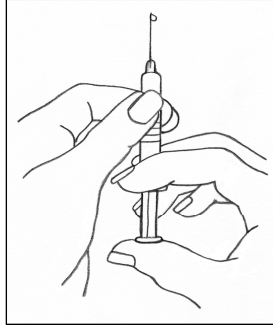


Figure 3

- Double-check that you have the right dose in the syringe. Lay the syringe down on its side until you have selected and prepared your injection site.

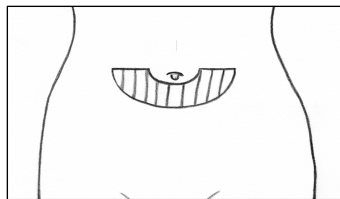
E. Selecting and Preparing the Injection Site

- Follistim AQ can be injected into your body using two different ways (routes) as described below. Follow your healthcare provider's instructions about how you should inject Follistim AQ.

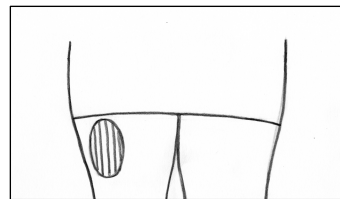
1. Subcutaneous Route:

For women and men:

- Follistim AQ can be injected directly into a layer of fat under your skin (subcutaneously).
- When giving a subcutaneous injection, follow your healthcare provider's instructions about changing the site for each injection. This will help lower your chances of having a skin reaction.
- **Do not** inject Follistim AQ into an area that is tender, red, bruised, or hard.
- Recommended sites for injecting Follistim AQ subcutaneously are:
 - Just below your belly button (navel) (See Figure 4)
 - The upper outer area of your thigh (See Figure 4)



Belly Button (navel)



Upper Outer area of the thigh

Figure 4

- Clean the skin with an alcohol wipe where the injection is to be made. Be careful not to touch the skin that has been wiped clean.
- Pick up the prepared syringe and needle and hold it in the hand that you will use to inject the medicine.
- Use the other hand to pinch a fold of skin at the cleaned injection site. **Do not** touch the cleaned area of skin.
- Hold the syringe like you would a pencil. Use a quick "dart-like" motion to insert the needle either straight up and down (90-degree angle) or at a slight angle (45-degree angle) (See Figure 5).

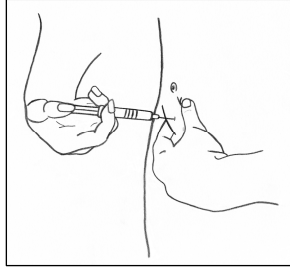


Figure 5

- Let go of the syringe and slowly pull back on the plunger. If blood comes into the syringe, **Do not** inject Follistim AQ because the needle might have entered a blood vessel.
- If no blood is seen and the needle is properly placed, push the plunger slowly and steadily to inject the Follistim AQ solution.
- Once you have injected the entire content of the syringe, pull the needle out of your skin and press a cotton ball or gauze over the injection site and hold it there for several seconds (See Figure 6).
- Gently massage the site while still maintaining pressure. This will help disperse the Follistim AQ solution and may relieve any discomfort.
- **Do not** put the needle cover (cap) back on the needle.

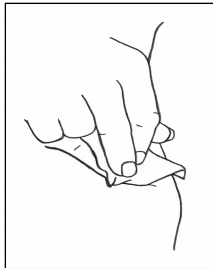


Figure 6

- Throw away the used needle and syringe in your puncture-proof container. (See "How Do I Throw Away Used Syringes and Needles?")
- For each injection, prepare a new syringe of Follistim AQ using the instructions above. Clean a new area of skin. In this new area of clean skin, again insert a new needle (as you did before), and again pull the plunger back slightly. If blood does not enter the syringe, inject the Follistim AQ by slowly pushing the plunger all the way down.
- Pull the needle out of your skin and press a cotton ball or gauze over the injection site and hold it there for several seconds. Do not put the needle cover (cap) back on the needle.
- Throw away the used needle and syringe in your puncture-proof container. (See "How Do I Throw Away Used Syringes and Needles?")

2. Intramuscular Route:

For women only:

- You will need to ask another person to give you your Follistim AQ injection intramuscularly (IM).
- Follistim AQ can be injected directly into your muscle (intramuscularly).
- When giving an intramuscular injection, follow your healthcare provider's instructions about changing the site for each injection. This will help lower your chances of having a skin reaction.
- **Do not** inject Follistim AQ into an area that is tender, red, bruised, or hard.
- Recommended site for injecting Follistim AQ intramuscularly is:
 - The upper outer area of the buttock (See Figure 7).

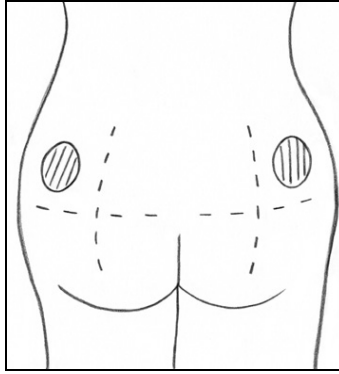


Figure 7

- Relax the muscle first by shifting your weight to the leg opposite of the side that the medicine will be injected into.
- Clean the skin with an alcohol wipe where the injection is to be made. Be careful not to touch the skin that has been wiped clean.

Instructions for giving an IM injection to the patient:

- Pick up the prepared syringe and needle and hold it in the hand that you will use to inject the medicine.
- Use the other hand to stretch a fold of skin at the cleaned injection site. Stretching the skin helps the needle to go in more easily and pushes the tissue beneath the skin out of the way. **Do not** touch the cleaned area of skin (See Figure 8).
- Hold the syringe like you would a pencil. Use a quick “dart-like” motion to insert the needle straight up and down (90-degree angle) (See Figure 8).

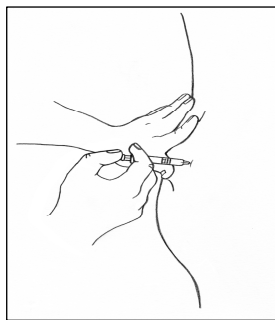


Figure 8

- Let go of the syringe and slowly pull back on the plunger. If blood comes into the syringe, **Do not** inject Follistim AQ because the needle might have entered a blood vessel.
- Pull the needle out of your skin and press a cotton ball or gauze over the injection site and hold it there for several seconds (See Figure 6).
- Gently massage the site while still maintaining pressure. This will help disperse the Follistim AQ solution and may relieve any discomfort.
- **Do not** put the needle cover (cap) back on the needle.
- Throw away the used needle and syringe in your puncture-proof container. (See “How Do I Throw Away Used Syringes and Needles?”)
- For each injection, prepare a new syringe of Follistim AQ using the instructions above. Clean a new area of skin. In this new area of clean skin, again insert a new needle (as you did before), and again pull the plunger back slightly. If blood does not enter the syringe, inject the Follistim AQ by slowly pushing the plunger all the way down.
- Pull the needle out of your skin and press a cotton ball or gauze over the injection site and hold it there for several seconds.
- **Do not** put the needle cover (cap) back on the needle.
- Throw away the used needle and syringe in your puncture-proof container. (See “How Do I Throw Away Used Syringes and Needles?”)

How Do I Throw Away Used Syringes and Needles?

Check with your healthcare provider or pharmacist for instructions about the right way to throw away used syringes and needles. There may be special local or state laws about how to throw away used syringes and needles.

- **Do not** throw away used syringes and needles in the household trash and do not recycle them.

- Put used and empty Follistim AQ syringes, needles, and vials in a closeable, puncture-resistant container. You may use a sharps container (such as a red bio-hazard container), a hard plastic container with a screw-on cap (such as an empty detergent bottle) or in a metal container with a plastic lid, (such as a coffee can).
- When the container is full, tape around the cap or lid to make sure the cap or lid does not come off.
- When your injection is given by another person, this person must also be careful when removing the syringe and needle and disposing of the syringe and needle to prevent accidental needle stick injury and passing infection.

How should I store Follistim AQ?

- Store Follistim AQ in the refrigerator at 2° - 8°C (36° - 46°F) until the expiration date.
- Follistim AQ can be stored at or below 25°C (77°F) for 3 months or until the expiration date, whichever comes first.
- Keep Follistim AQ away from light.
- Do not freeze.

Keep Follistim AQ, syringes, needles, and the disposal container out of the reach of children.

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For patent information: www.merck.com/product/patent/home.html

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