

Instructional Quick Guide

▶ **READY** ▶ **SET** ▶ **INJECT**



- Always use Follistim[®] AQ Cartridge as prescribed for you by your health care provider.
- Your dose may be increased or decreased as your treatment progresses.
- Do not inject Follistim[®] AQ Cartridge until you have received instruction from your health care provider regarding the administration of Follistim[®] AQ Cartridge.
- Close care by your health care provider is very important.

To give yourself the injection, you will need:

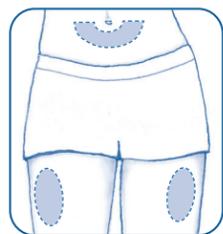
- Follistim Pen[®], a Follistim[®] AQ Cartridge (follitropin beta injection), a new BD Micro-Fine[™] Pen Needle provided with the Cartridge
- Alcohol and cotton balls, or alcohol pads, sterile gauze, anti-bacterial soap, and a safety container to discard used supplies
- The Follistim Pen[®] Treatment Diary/Follistim Pen[®] Instructions for Use booklet provided with the Follistim Pen[®]

Before you begin

The Follistim Pen[®] is only for use with the Follistim[®] AQ Cartridge when prescribed for subcutaneous injection. Read all instructions carefully before using your Follistim Pen[®] with Follistim[®] AQ Cartridge. Failure to do so could result in an incorrect dose being given.

Keep a record of every injection that has been taken from a Follistim[®] AQ Cartridge. In your Follistim Pen[®] Treatment Diary:

- Record your prescribed daily dose and the "deliverable content" of each Follistim[®] AQ Cartridge. "Deliverable content" is labeled on every cartridge (either 300 IU, 600 IU or 900 IU).
 - Subtract your prescribed daily dose from the "deliverable content." Record the amount of medicine left in the Follistim[®] AQ Cartridge for use in your next dose.
- ✓ Check the medicine in your Follistim[®] AQ Cartridge—if it contains particles or is not clear, **DO NOT USE**.
 - ✓ Allow the medicine to reach room temperature before use, to decrease possible discomfort.
 - ✓ Wash your hands thoroughly with soap and water.
 - ✓ Select your injection site:



Follistim[®] AQ Cartridge is given by injection just under the skin (subcutaneous injection).

Recommended sites are the area just below the belly button or the upper thigh.

When injecting beneath the skin, always fully depress the injection button for a full 5 seconds. During these 5 seconds, leave the needle in the skin to ensure delivery of the full dose.

Only attach the needle when you are ready to inject. Each BD Micro-Fine[™] Pen Needle is for one injection only. The needle is for use only with the Follistim Pen[®]. Always remove the needle from the Follistim Pen[®] immediately and dispose of it properly in its Outer Needle Shield after you complete your injection.

Proper procedures should be used for the disposal of the used needles (fixed in the Outer Needle Shield), empty cartridges, and left over medication. Consult your health care provider for proper disposal procedures.

Follistim Pen[®] is designed for use by one person only and should not be shared with others. The Follistim Pen[®] is not recommended for the blind or visually impaired user without the assistance of an individual with good vision, trained in the proper use of the injection device. The Follistim Pen[®] is intended for self-injection of Follistim[®] AQ Cartridge. If you are giving an injection to another person, be very careful when removing the needle from the skin. Accidental needle sticks can transmit infectious diseases.

Please turn page →

Please see accompanying full Prescribing Information for Follistim[®] AQ Cartridge. This instruction sheet complements, but does not replace instructions by your health care provider regarding the administration of Follistim[®] AQ Cartridge with Follistim Pen[®]. It should be used after receiving instruction from your health care provider. This instruction sheet is provided as an educational service by Schering Corporation.

Follistim[®] AQ Cartridge (follitropin beta injection) is approved to help women who have problems with ovulation. Follistim[®] AQ Cartridge will not help women whose ovaries do not work at all (primary ovarian failure). Follistim[®] AQ Cartridge is also for women that are in an assisted reproductive technology (ART) program, such as *in vitro* fertilization.

Important Safety Information:

Always follow your health care professional's dosing instructions when administering Follistim[®] AQ Cartridge. Your health care professional has individualized the dose to be administered based on your medical history. Do not change your dose unless instructed by your health care professional.

Do not use Follistim[®] AQ Cartridge if you are allergic to recombinant human FSH products; have primary ovarian failure (your ovaries do not work at all); are pregnant or think you might be pregnant; have uncontrolled thyroid or adrenal gland problems; have tumors in your ovaries, breasts, uterus, hypothalamus, or pituitary gland; have heavy or irregular vaginal bleeding and the cause is not known; have ovarian cysts or enlarged ovaries not due to polycystic ovary syndrome (PCOS); or are allergic to streptomycin or neomycin. Follistim[®] AQ Cartridge may contain traces of these antibiotics and may cause allergic reactions.

Follistim[®] AQ Cartridge may cause ovarian hyperstimulation syndrome (OHSS), which is a serious medical problem that can happen when the ovaries are overstimulated. In rare cases it has caused death. OHSS causes fluid to build up suddenly in the stomach and chest areas. OHSS may occur after treatment with Follistim[®] AQ Cartridge. Call your health care professional right away if you get any of the following symptoms: severe pelvic pain (lower stomach area), nausea, vomiting, sudden weight gain, or reduced urine output.

Follistim[®] AQ Cartridge and other FSH products may cause serious lung problems including fluid in the lungs, trouble breathing, and worsening of asthma. Follistim[®] AQ Cartridge and other FSH products may also cause blood clots in blood vessels. This can lead to blood vessel problems (thrombophlebitis), stroke, loss of limb, or a blood clot in the lung (pulmonary embolus).

Follistim[®] AQ Cartridge and other FSH products can cause multiple births. Your health care professional will discuss your chances of multiple births.

Follistim[®] AQ Cartridge should only be prescribed by physicians experienced in infertility treatments.

Other side effects with Follistim[®] AQ Cartridge include stomach pain, gas, pelvic pain, nausea, breast pain, injection site problems, enlarged stomach area, back pain, constipation, headache, and ovarian pain. If you get any side effects that concern you, call your health care professional. These are not all the side effects of Follistim[®] AQ Cartridge. Contact your doctor or other health care professional without delay if you are experiencing symptoms including significant abdominal pain or if symptoms develop some days after the last injection has been given.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please see accompanying important product information.



For more information, call 1-866-836-5633 or visit www.follistim.com.
 For support services, please visit www.fertilityjourney.com.

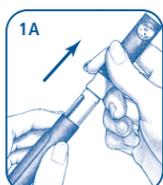
Using Your Follistim[®] AQ Cartridge with the Follistim Pen[®]

(follitropin beta injection)

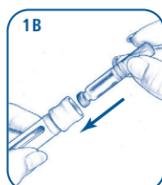
The directions provided in this instruction sheet are an abbreviated version. They should be used only after receiving directions from your health care professional and carefully reading the complete Patient Information Leaflet and all Instructions for Use. Do not inject Follistim AQ[®] Cartridge until your health care professional has taught you the correct way.

READY ▶ Prepare your Follistim Pen[®].

Follow this step when you use your Follistim Pen[®] for the first time, or when you replace the Cartridge.



- Pull the Protective Cap off the Pen Body and put it aside on a clean, dry surface.
- Unscrew the entire Pen Body from the Cartridge Holder.
- Place Pen Body and Cartridge Holder on a clean, dry surface.



- Remove the Follistim AQ[®] Cartridge from its package and clean the rubber inlay of the Cartridge with an alcohol pad.
- Insert the Cartridge into the Cartridge Holder, metal rimmed cap end first.



- Screw Pen Body fully onto the Cartridge Holder containing the inserted Cartridge, making sure there are no gaps.
- Line up the arrow (▶) with the middle of the yellow alignment mark (■).



- Clean the open end of the Cartridge Holder with an alcohol pad. Peel off the protective paper shield from the Pen Needle Outer Needle Shield. Push the end of the Cartridge Holder into the Outer Needle Shield. Screw tightly together.
- **Your Follistim Pen[®] is now assembled and loaded.**
- **Never touch the needle and never place an open needle on any surface.**

SET ▶ Set your dose.



- Gently pull off the Outer Needle Shield, leaving the Inner Needle Shield in place, and set aside. *Do not discard the Outer Needle Shield.*
- Use an alcohol pad to clean about a two-inch area of skin where the needle will enter. Let dry at least a minute.



- Carefully remove the Inner Needle Shield and discard. **Do not touch the needle or let it touch any surface while uncapped.**



- Hold Follistim Pen[®] with the needle pointing up. Tap Cartridge Holder with your finger to force air bubbles to top.
- Dial Dosage Knob until you hear one click. With the needle pointing upwards, push in the Injection Button.
- Look for a droplet of medicine at needle tip. If you do not see a droplet, repeat above, otherwise, you may not receive the correct dose.
- If you have already used the Follistim[®] AQ Cartridge and you need to give yourself another dose, attach a new BD Micro-Fine[™] Pen Needle and look for a droplet forming at the tip of the needle. If you do not see a droplet, repeat step 2C.



- For doses of 50 IU up to 450 IU, turn Dosage Knob until the dosage aligns with the dosage markers on each side of the Dosage Window.
- *If you dial past your dose, do not turn Dosage Knob back (you will not damage the Pen, but medicine will be lost).*
- Continue turning until you pass the 450 IU mark, as far as it will turn. The Dosage Knob must move freely.
- Push the Injection Button in as far as it will go. Start dialing from "0" upwards until you reach the correct dosage.
- **You are now ready to complete your injection.**
- **Never try to correct a dose-dialing mistake while the needle is in your skin. This may result in an incorrect dose.**

INJECT ▶ Inject your Follistim[®] AQ Cartridge.



- Pinch the cleansed skin area between two fingers. With your other hand, insert entire Pen Needle straight into the skin. Press Injection Button all the way. Wait 5 seconds. Pull needle out quickly and apply pressure to injection site with an alcohol pad. Maintaining pressure, gently massage the site.
- The best places to inject are your abdomen and your upper thigh.
- *If the dot next to the "0" is not in the middle of the Dosage Window and you cannot push the Injection Button all the way in, do not try to force down the button. Your Follistim[®] AQ Cartridge is probably empty. This means you have not received your full dose. Do not adjust the setting on the Dosage Scale. The number in the Dosage Window is the amount needed to complete your prescribed dose. Write down this number. Remove the needle and dispose of it properly. Reset the Dial Window to "0", by turning the Dosage Knob past the 450 IU mark as far as it will turn and pushing the injection button in all the way. Repeat instructions from "Ready (▶) Prepare your Follistim Pen[®]" to load a new cartridge, attach a new needle and inject the remaining drug to complete your dose.*
- **Your injection is complete!**

Storage and disposal

- Each Pen Needle is for one injection only. Immediately following injection, remove and dispose of the used Pen Needle. The Pen Needle must be removed from the Follistim Pen[®] prior to storage. See the Patient Information Leaflet and Follistim Pen[®] Treatment Diary/Instructions for Use booklet provided with the Follistim Pen[®] for complete instructions on needle removal and Pen storage.
- Dispose of all used supplies in safety container, as recommended by your health care provider.



For more information, call 1-866-836-5633 or visit www.follistim.com.
For support services, please visit www.fertilityjourney.com.