

PATIENT INFORMATION LEAFLET

Follistim® AQ Cartridge

(follitropin beta injection)

Read the patient information carefully before you start using Follistim® AQ (fol-i-stim) Cartridge (follitropin beta injection) with Follistim Pen® and each time you get a refill. There may be new information. This information does not take the place of talking with your healthcare professional about your medical condition or treatment.

What is Follistim® AQ Cartridge?

Follistim® AQ Cartridge (follitropin beta injection) is a medicine that contains the follicle-stimulating hormone (FSH). FSH helps (stimulate) healthy ovaries to make eggs.

What is Follistim® AQ Cartridge used for?

Doctors specializing in treating women who have problems getting pregnant use Follistim® AQ Cartridge (follitropin beta injection) for the patient who needs medical help to have a child because that patient:

- a. has problems with ovulation (producing and releasing eggs). Follistim® AQ Cartridge will not help women whose ovaries do not work at all (primary ovarian failure).
- b. is participating in an Assisted Reproductive Technology (ART) program, such as *in vitro* fertilization, to help her ovaries make more eggs.

Follistim® AQ Cartridge should be used only for women seeking to become pregnant. Follistim® AQ Cartridge may be one of several drugs prescribed to you as part of your treatment program. Always follow your doctor's dosing instructions when administering Follistim® AQ Cartridge. Your doctor has individualized the dose to be administered based on your medical history. Do not change your dose unless instructed by your doctor.

Who should not take Follistim® AQ Cartridge?

Do not use Follistim® AQ Cartridge (follitropin beta injection) if you:

- are allergic to recombinant human FSH products (see the end of this leaflet for a list of all the ingredients in Follistim® AQ Cartridge)
- 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)
- are allergic to streptomycin or neomycin. Follistim® AQ Cartridge may contain traces of these antibiotics and may cause allergic reactions.

Tell your healthcare provider if you are breast-feeding. It is not known if the active ingredient of Follistim® AQ Cartridge passes into your milk.

What are the possible side effects of Follistim® AQ Cartridge?

Follistim® AQ Cartridge (follitropin beta injection) and other FSH products may cause serious side effects including:

- **Ovarian Hyperstimulation Syndrome (OHSS).** OHSS 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.
Stop using Follistim® AQ Cartridge and call your healthcare provider right away if you get any of the following symptoms:
 - severe pelvic pain (lower stomach area)
 - nausea
 - vomiting
 - sudden weight gain
 - reduced urine output.
- **Lung and blood vessel problems.** 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).
- **Multiple births.** Follistim® AQ Cartridge and other FSH products can cause multiple births. Your healthcare provider will discuss your chances of multiple births.

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 healthcare provider.

These are not all the side effects of Follistim® AQ Cartridge. Contact your doctor or other healthcare provider without delay if you are experiencing symptoms including significant abdominal pain, or if symptoms develop some days after the last injection has been given (see “Who should not take Follistim® AQ Cartridge?”).

How should I use Follistim® AQ Cartridge?

- Your healthcare professional will decide on the dose of Follistim® AQ Cartridge (follitropin beta injection) that is best for you. This dose may be increased or decreased as your treatment goes on. This will depend on your type of treatment. It is very important that you follow your healthcare professional's instructions exactly.
- Follistim® AQ Cartridge is given by an injection just under the skin (subcutaneous injection).

Your healthcare provider will teach you how to inject yourself. See the end of this leaflet for “INSTRUCTIONS FOR USE”. Do not inject Follistim® AQ Cartridge at home until your healthcare professional's office has taught you the right way.

Close care by your healthcare professional is very important. Usually, ultrasound scans of the ovaries are regularly made. Blood or urine samples are regularly taken. The results of these tests allow your healthcare professional to choose the right dose of Follistim® AQ Cartridge for you each day. This is very important. Too high a dose of FSH may lead to rare, but serious problems in which the ovaries become overstimulated (too active). This may be noticed as pain in the abdomen (stomach area). Regular checking of your response to FSH treatment helps your healthcare professional lower your chances of ovarian overstimulation. Call your healthcare professional right away if you get strong abdominal pain. Also call your healthcare professional right away if this happens some days after the last injection has been given.

Dosage

• **Assisted Reproductive Technologies (ART)**

A starting dose of Follistim® AQ Cartridge (follitropin beta injection) will be prescribed by your healthcare professional based upon review of your medical history. This starting dose of Follistim® AQ Cartridge to be injected with the Follistim Pen® under the skin is usually recommended for at least the first 5 days of treatment. After this, your healthcare professional may adjust your dose based upon how your ovaries are responding to Follistim® AQ Cartridge. When an ultrasound examination shows that you are ready, another drug (hCG) may be injected to induce the final maturation of the follicles.

• **Ovulation Induction (OI)**

A starting dose of Follistim® AQ Cartridge (follitropin beta injection) will be prescribed by your healthcare professional based upon review of your medical history. This starting dose of Follistim® AQ Cartridge to be injected with the Follistim Pen® under the skin is usually recommended for at least 7 days. Your healthcare professional may then adjust the dose based upon how your ovaries are responding to Follistim® AQ Cartridge. When an ultrasound examination shows that you are ready, another drug (hCG) may be injected to induce ovulation.

WHAT YOU WILL NEED FOR GIVING YOURSELF THE INJECTION

- Follistim Pen®, a Follistim® AQ Cartridge (follitropin beta injection), the BD Micro-Fine™ Pen Needle provided with the cartridge.
- Alcohol, cotton balls or alcohol pads/swabs, sterile gauze, antibacterial soap and a special safety container to discard the used needles, cartridges and/or other supplies.

IMPORTANT NOTICE

Please read all instructions for the use of the Follistim Pen® before administering the Follistim® AQ Cartridge.

1. The Follistim Pen® is a precision injection device which is only to be used with the Follistim® AQ Cartridge. It is very important that you read and follow all directions for its use. As with all injection systems, failure to do so could result in an incorrect dose being given.
2. Injecting cold drug is likely to cause discomfort. Therefore, it is recommended you allow the drug to reach room temperature before taking the injection. The needle should not be attached until just before the injection.
3. 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 of Follistim® AQ Cartridge (follitropin beta injection).
4. Follistim Pen® is designed for use by one person only and should not be shared with others.
5. The BD Micro-Fine™ Pen Needle is for use only with Follistim Pen®. Each BD Micro-Fine™ Pen Needle is for one injection only.
6. 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.
7. Keep a record of every injection that has been taken from a Follistim® AQ Cartridge. A patient diary is available with the Instructions for Use Manual. This will allow you to calculate the daily amount of medication remaining in the cartridge by subtracting the injected amount from the 150 IU (orange), 300 IU (silver), 600 IU (gold) and/or 900 IU (blue) as indicated as the content on the cartridge label.
8. Your healthcare professional will decide on the dose of Follistim® AQ Cartridge to be given. This dose may be increased or decreased as your treatment progresses depending on your individual type of treatment. If you have previously used gonadotropins, your dose may be different with Follistim® AQ Cartridge. Again, your healthcare professional will decide the dose based upon your medical history.

INSTRUCTIONS FOR USE

BEFORE USING FOLLISTIM PEN® FOR THE FIRST TIME, READ THESE INSTRUCTIONS CAREFULLY. THEY ARE DIVIDED INTO SECTIONS. EACH SECTION HAS A NUMBER OF STEPS. KEEP THIS LEAFLET IN A SAFE PLACE AND REFER TO IT WHEN QUESTIONS ARISE.

The main actions contained in this patient leaflet that must be learned are:

1. **Loading the Follistim Pen®**
2. **Dialing the prescribed dose**
3. **Using the Follistim Pen® to give yourself an injection of Follistim® AQ Cartridge**

The Follistim Pen® is a very precise injection device. It is easy to use and convenient. The special features allow you to inject Follistim® AQ Cartridge safely and effectively.

Follistim® AQ Cartridge using Follistim Pen® can be administered in prescribed doses from 50 International Units (IU) up to 450 IU, in marked 25 IU increments. The Dosage Scale on the Pen has easy-to-read numbers and audible clicks to help you set the correct dose. Incorrect settings are easily corrected without loss of drug.

- Follistim® AQ Cartridges and BD Micro-Fine™ Pen Needles may only be used with Follistim Pen®.
- Do not separate the three parts of the Follistim Pen®, shown below, until told to do so in the instructions.

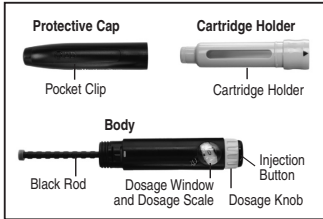
INJECTION INSTRUCTIONS FOR FOLLISTIM® AQ CARTRIDGE WITH THE FOLLISTIM PEN®

Carefully read these instructions before injecting Follistim® AQ Cartridge with the Follistim Pen®. Do not use Follistim® AQ Cartridge with the Follistim Pen® unless your healthcare professional has taught you the right way to inject it and you understand everything. Ask your healthcare professional if you have any questions.

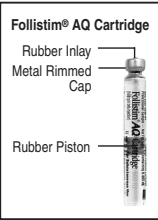


Figure shown not actual size

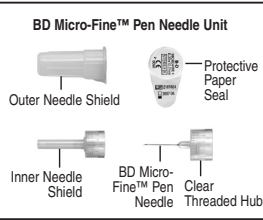
Follistim Pen® Parts



Follistim® AQ Cartridge



BD Micro-Fine™ Pen Needle Unit Parts



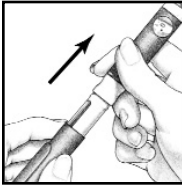
USING THE FOLLISTIM PEN®

Follow these steps:

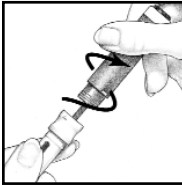
- Before you use the Follistim Pen® for the first time
- When you replace the cartridge

Note: Always wash your hands thoroughly with antibacterial soap and water before you use the Follistim Pen® or when you replace the cartridge.

1. While holding the Pen Body firmly with one hand, pull off the Protective Cap with your other hand. Put the cap aside on a clean, dry surface.

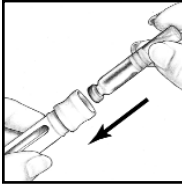


2. Unscrew the entire Pen Body from the Cartridge Holder. Place the Cartridge Holder and the Pen Body aside on a clean, dry surface.

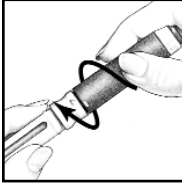


LOADING THE FOLLISTIM PEN®

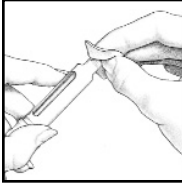
3. Take the correct size Follistim® AQ Cartridge (i.e., 150 IU, 300 IU, 600 IU or 900 IU) out of its package as prescribed by your healthcare professional. Do not use the Follistim® AQ Cartridge if the medicine contains particles or it is not clear. Make sure the medicine is at room temperature before using. Clean the Rubber Inlay on the cartridge with an alcohol pad. Pick up the Cartridge Holder and place the cartridge into the Cartridge Holder. Insert the Metal Rimmed Cap end first.



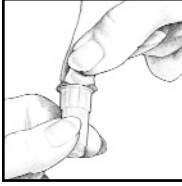
4. Pick up the Pen Body and lower it into the Cartridge Holder. The black rod must press against the Rubber Piston on the cartridge. Screw the Pen Body fully onto the Cartridge Holder. Make sure there is no gap between the Pen Body and the Cartridge Holder. The arrow (▲) on the Cartridge Holder should point to the middle of the yellow alignment mark (■) on the blue Pen Body.



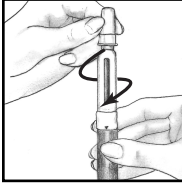
5. You must use a new BD Micro-Fine™ Pen Needle with each injection. Never reuse a needle. Attach a BD Micro-Fine™ Pen Needle after you make sure there is a Follistim® AQ Cartridge in the Cartridge Holder. Clean the open end of the Cartridge Holder with an alcohol pad.



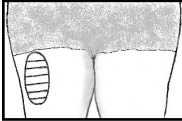
6. Pick up your BD Micro-Fine™ Pen Needle that is in an Outer Needle Shield. Peel off the protective paper seal. Do not touch the needle or place an open needle on any surface.



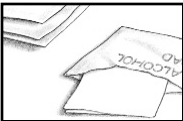
7. Hold the Outer Needle Shield firmly in one hand while holding the Cartridge Holder firmly in the other hand. Push the end of the Cartridge Holder into the Outer Needle Shield. Screw them tightly together. Place your Follistim Pen® with the attached needle, flat on a clean, dry surface.



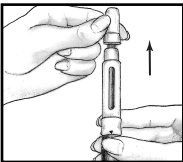
8. The best place for injection is in the abdomen, which is the stomach area below the belly button (navel) or in the upper leg. Your healthcare professional can show you other places where you can inject Follistim® AQ Cartridge. Change your injection site a little bit with each injection to lower your chances for skin reactions.



9. Use a swab moistened with alcohol to clean the skin area where the needle will enter to remove any surface bacteria. Clean about two inches around the injection site where the needle will be inserted. Let the alcohol dry on your skin for at least one minute before injecting the medicine.

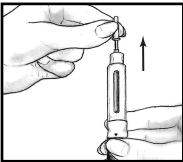


10. Pull the Outer Needle Shield gently, leaving the Inner Needle Shield in place (covering the needle, which is now attached to the Pen). **Do not throw the Outer Needle Shield away.** You will need it to dispose of the needle after injecting the medicine. Instructions for disposing the needle are given later in this leaflet.

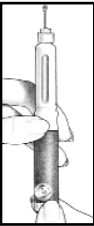


Important:

- **Do not touch the needle or leave it uncapped without Inner Needle Shield** so that it remains sterile.
- **Use a new, sterile BD Micro-Fine™ Pen Needle for each injection. Only use the BD Micro-Fine™ 0.33 mm x 12.7 mm (29G) Pen needles as supplied with the Folllistim AQ Cartridge.**



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



12. Hold the Folllistim Pen® with the needle pointing upwards. Tap the Cartridge Holder gently with your finger to help air bubbles rise to the top of the needle. The small amount of air bubble will not affect the amount of medicine you receive.

If you have loaded a new, unused cartridge into the Folllistim Pen®, always follow these steps:

- a. Dial the Dosage Knob until you hear one click. With the needle pointing upwards, push in the Injection Button.
- b. Look for a droplet at the tip of the needle.
- c. If you still do not see a droplet, repeat Step a. (above) until you see droplet. You must make sure you see a droplet of medicine or you may not inject the correct amount of medicine.

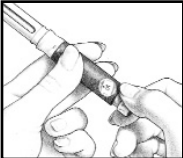
If you have already used the Folllistim AQ Cartridge and you need to give yourself another dose, simply attach a new BD Micro-Fine™ Pen Needle and look for a droplet forming at the tip of the needle. If you see a droplet, go to Step 13. If no droplet is seen, follow Steps a, b and c above.

Important:

- **Steps a, b and c need to be performed every time you load a new, unused cartridge in the Folllistim Pen®.**
- **Always check the drug flow by following the directions in Step 12. This will ensure that the correct dose of Folllistim AQ Cartridge is injected. If you do not check drug flow, you could receive less drug than the dose that you dialed.**

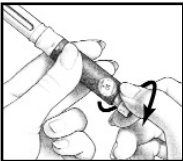
DIALING THE PRESCRIBED DOSE

13. Your Folllistim AQ Cartridge will contain one of the following color-coded cartridge sizes: 150 IU (orange), 300 IU (silver), 600 IU (gold) or 900 IU (blue). Record the Folllistim AQ Cartridge content in your Folllistim Pen® Treatment Diary (refer to CHECKING THE DRUG LEVEL for more information). For doses of 50 IU up to 450 IU, turn the Dosage Knob until the dot beside the correct number on the Dosage Scale is sitting in the middle of the Dosage Window.



14. If by mistake you dial past the correct number, **do not try to turn the Dosage Knob backward to fix the mistake.** Continue to turn the Dosage Knob in the same direction past the 450 IU mark, as far as it will turn. The Dosage Scale must move freely. Push the Injection Button in all the way. Start to dial again starting from “0” upwards.

By following these directions, you will not lose any medicine from the Folllistim AQ Cartridge.



Important:

- **If you turn the Dosage Knob backward to correct the mistake, it will not damage the Pen, but you will lose some medication from the Folllistim AQ Cartridge.**
- **Never dial your dose or try to correct a dialing mistake when the needle is still in your skin as this may result in your receiving an incorrect dose.**
- **If your prescribed dose exceeds the deliverable dose of Folllistim Pen® or exceeds the amount remaining in the cartridge, you will need to give yourself more than one injection.**



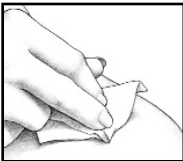
USING THE FOLLISTIM PEN® TO GIVE YOURSELF AN INJECTION OF FOLLISTIM AQ CARTRIDGE

Once you have set the Folllistim Pen® to the correct dose, you are ready for your injection.

15. Pinch the already swabbed area of the skin between two fingers. With the other hand, insert the entire BD Micro-Fine™ Pen Needle straight into the skin. Press the injection button all the way in to make sure you give yourself a full injection. Wait for five seconds before pulling the needle out of the skin. The middle of the Dosage Window should display a dot next to the “0”. If the injection button does not push in all the way, and the number in the Dosage Window does not read “0”, it means there is not enough medication left in the cartridge to complete your prescribed dose. The number in the Dosage Window will give you the amount of medicine needed to complete your dose. Write this number down. This will be the number you dial for the completion of your dose. Start over with a new Folllistim AQ Cartridge and a new needle and follow all the instructions up to this step. Make sure you choose a different injection site to complete your dose of Folllistim AQ Cartridge.



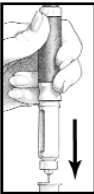
16. Pull out the BD Micro-Fine™ Needle and firmly press down on the injection site with an alcohol swab. Use the BD Micro-Fine™ Pen Needle for one injection only.



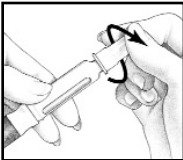
Important:

- **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 Folllistim AQ Cartridge is probably empty. This means you have not received your full dose. Do not adjust the setting on the Dosage Scale. Follow the instructions for IF THERE IS NOT ENOUGH FOLLISTIM AQ IN THE CARTRIDGE.**

17. Place the Outer Needle Shield on a flat table surface with the opening pointing up. The opening of the Outer Needle Shield is the wider end with the rim. Without holding on to the Outer Needle Shield, carefully insert the needle (attached to the Folllistim Pen®) into the opening of the Outer Needle Shield and push down firmly. The Outer Needle Shield should now be attached to the Cartridge Holder and cover the needle.



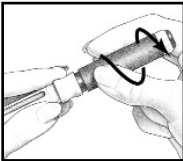
18. Grip the Outer Needle Shield and use it to unscrew the needle from the Cartridge Holder. Your healthcare professional can advise you on how to obtain a special container for proper needle disposal. Safely, dispose the Outer Needle Shield with the used needle right away. Do not throw away in a trash can. If there is Folllistim AQ Cartridge medicine left for more injections, put the Pen Cap back on the Pen Body and store your Folllistim Pen® in a safe place in the refrigerator (**not in the freezer**) or at room temperature. **Never store the Folllistim Pen® with a needle attached to it.** If you are giving an injection to another person, be very careful when removing the needle from the skin. Accidental needle sticks can transmit potentially serious or grave infectious diseases.



Important:

- **Use the BD Micro-Fine™ Pen Needle for one injection only.**
- **Dispose of the used needle inside the Outer Needle Shield immediately in a properly secured container as instructed by your healthcare professional. Never leave needles where anyone can accidentally prick themselves.**
- **Always unscrew the needle by following the directions in Steps 17 and 18 before you put the Folllistim Pen® away.**
- **Never store the Folllistim Pen® with a needle attached to it. If you store the Folllistim Pen® with the needle attached, the drug could leak out and there is risk of contamination.**
- **Never leave needles where others can pick them up.**

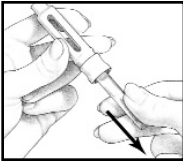
19. Before you remove the empty Folllistim AQ Cartridge from the Folllistim Pen®, unscrew the needle by following Steps 17 and 18. Unscrew the Pen Body from the Cartridge Holder.



20. Put the Pen Body down on a clean, dry surface and remove the empty Folllistim AQ Cartridge from the Cartridge Holder. Safely, dispose of the empty Folllistim AQ Cartridge right away in the same special container that you used for the needle disposal. Do not put the cartridge in a trash can.

Now, you may either:

- Put the Folllistim Pen® back together without a Folllistim AQ Cartridge and store for your next injection **OR**
- Insert a new Folllistim AQ Cartridge into the Cartridge Holder, put your Folllistim Pen® back together, and store safely in the refrigerator or at room temperature.



CHECKING THE DRUG LEVEL

When you are advised on the number of prescribed doses which can be extracted from the full unused Folllistim AQ Cartridge (folllistropin beta injection), then do not use the cartridge beyond the advised number of doses. Otherwise, you will run the risk that there will not be enough volume of drug for your prescribed dose.

Starting with the initial injection, you should begin using your Folllistim Pen® Treatment Diary as follows:

- a. Record the Folllistim AQ Cartridge content. This will either be 150, 300, 600 or 900 IU depending on what your healthcare professional has prescribed for you.
- b. Record the daily dose you have been prescribed for your injection.
- c. Subtract your Day 1 dose from the Folllistim AQ Cartridge deliverable content (150, 300, 600 or 900 IU) (see example below). This will give you the remaining Folllistim AQ Cartridge content.

After Day 1, continue to record your daily injections in your Treatment Diary as follows:

- d. Place the number recorded on Day 1 in the remaining Folllistim AQ Cartridge contents box in the Day 2 Folllistim AQ Cartridge content box.
- e. Subtract your Day 2 dose from the Folllistim AQ Cartridge content you just recorded in Step d. This will give you the remaining Folllistim AQ Cartridge content. Again, record this number in the correct box.

Date	Daily Dose to be Used (IUs/day)	Folllistim AQ Cartridge Content	Remaining Folllistim AQ Cartridge Content
mm/dd/yy	150	600	450
mm/dd/yy	150	450	300
mm/dd/yy	150	300	150

If there is any doubt that there is not enough drug in the Folllistim AQ Cartridge for your prescribed dose, see section 'IF THERE IS NOT ENOUGH FOLLISTIM AQ IN THE CARTRIDGE'.

IF THERE IS NOT ENOUGH FOLLISTIM AQ IN THE CARTRIDGE

If you realize before you inject that you do not have enough drug remaining in your Folllistim AQ Cartridge for your complete dose, proceed to Step 1 (below).

OR

If you have already inserted the needle at the injection site and the Injection Button will not push in all the way, then there is not enough drug contained in the cartridge. The number in the Dosage Window will not read “0” – this means that there is not enough drug remaining in the Folllistim AQ Cartridge to complete your dose. In this case, proceed to Step 2 (below).

Important:

- **When there is not enough drug contained in the Folllistim AQ Cartridge to complete your injection, the Injection Button will not push in all the way and the number in the Dosage Window will not read “0”. If this occurs, proceed with the steps that follow.**

1. If you realize you do not have enough drug remaining in your Folllistim AQ Cartridge, you have 2 options:

Option #1: Remove the Folllistim AQ Cartridge as outlined in Steps 19 and 20. Insert a new cartridge into the Folllistim Pen® (see Steps 3 and 4). Continue with Steps 5 – 18 for your injection.

Option #2: Dial your dose and inject the remaining content in the Folllistim AQ Cartridge. The Dosage Knob Injection Button will not push in all the way and the Dosage Window number will not read “0” but will read the number of units you will need to complete your prescribed dose. Remember to write down the number of units needed to complete your dose. Remove the needle and dispose of it properly as outlined in Steps 17 and 18. Using the Dosage Knob, reset the Dial Window to “0” by turning the Dosage Knob past the 450 IU mark as far as it will turn and push the Injection Button in all the way. Insert a new cartridge into the Folllistim Pen® and attach a new BD Micro-Fine™ needle (see Steps 3 – 12). Dial to the number of units you have written down to complete your prescribed dose. Prepare a different injection site and inject the remaining drug to complete your dose (refer to USING THE FOLLISTIM PEN® TO GIVE YOURSELF AN INJECTION OF FOLLISTIM AQ CARTRIDGE).

2. If you have already inserted the needle at the injection site, inject the remaining content in the Folllistim AQ Cartridge. The Injection Button will not push in all the way and the number in the Dosage Window will not read “0” but will read the number of units you will need to complete your prescribed dose. Wait 5 seconds before withdrawing the needle from your skin and gently apply pressure to the injection site with an alcohol pad. Dispose the used needle properly as outlined in Steps 17 and 18. Remember to write down the number of units needed to complete your dose. Using the Dosage Knob, reset the Dial Window to “0” by turning the Dosage Knob past the 450 IU mark as far as it will turn and push the Injection Button in all the way. Insert a new cartridge into the Folllistim Pen® and attach a new BD Micro-Fine™ needle (see Steps 3 – 12). Dial to the number you have recorded to complete your prescribed dose. Prepare a different injection site and inject the remaining drug to complete your dose (refer to USING THE FOLLISTIM PEN® TO GIVE YOURSELF AN INJECTION OF FOLLISTIM AQ CARTRIDGE).

GENERAL INFORMATION ABOUT THE FOLLISTIM AQ CARTRIDGE

Ingredients in Folllistim AQ Cartridge

Folllistim AQ Cartridge contains the active ingredient folllistropin beta. Inactive ingredients in the cartridges include: sucrose, sodium citrate, polysorbate, benzyl alcohol, L-methionine, water for injection, hydrochloric acid and/or sodium hydroxide.

Caring for the Folllistim Pen®

1. Clean all exposed surfaces of the Folllistim Pen® with a clean, damp cloth such as a paper towel. Never wash it in water, detergent or strong medical cleaners.
2. Handle the Folllistim Pen® carefully to avoid causing damage. You could damage the Folllistim Pen® by dropping it or handling it roughly.
3. Keep the Folllistim Pen® away from dust and dirt.
4. If the Folllistim Pen® breaks or is damaged, do not try to fix it yourself. Contact your healthcare professional.
5. Do not share your Folllistim Pen® with another person.

Storing the Folllistim Pen®

1. Store refrigerated, 2–8°C (36–46°F) until dispensed. Do not freeze. Upon dispensing, the product may be stored by the patient at 2–8°C (36–46°F) until the expiration date, or at 25°C (77°F) for 3 months or until the expiration date, whichever occurs first. Once the rubber inlay of the Folllistim AQ Cartridge has been pierced by a needle, the product may be stored only for a maximum of 28 days at 2–25°C (36–77°F).

For proper storage of unused Folllistim AQ Cartridges, please see the package insert enclosed with Folllistim AQ Cartridges.

2. Folllistim Pen® with a Folllistim AQ Cartridge should be protected from light.
3. Do not use past the indicated expiration date on the Folllistim AQ Cartridge.
4. Keep the Folllistim Pen®, Folllistim AQ Cartridge, and any other components out of the sight and reach of children.
5. After your treatment is finished, store the Folllistim Pen® injection device as instructed by your healthcare professional.

PRECAUTIONS

- **Do not share your Folllistim Pen® with another person.**
- **The Folllistim 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 Folllistim Pen® is only indicated for use with a Folllistim AQ Cartridge when prescribed for subcutaneous injection.**

Care while using the BD Micro-Fine™ Pen Needle

- Only attach the BD Micro-Fine™ Pen Needle when you are ready to inject. Always remove the needle from the Folllistim Pen® immediately and dispose of it properly in its Outer Needle Shield after you complete your injection.
- The Pen Needle Unit is sterile. To avoid contaminating the needle after opening, do not place it on any surface or touch exposed parts.
- Before attempting to replace a Folllistim AQ Cartridge, be sure that a BD Micro-Fine™ Pen Needle is not attached to the Folllistim Pen®.
- Never dial your dose or attempt to correct a dialing error with the needle in your skin, as this may result in an incorrect dose.
- Proper procedures should be used for the disposal of the used needles (fixed in the Outer Needle Shield), “empty” cartridges, and leftover medication. Consult your healthcare professional on the proper procedures for disposal.
- The Folllistim Pen® is intended for self-injection of Folllistim 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.

While this leaflet summarizes important information about Folllistim AQ Cartridge, it does not contain all of the possible precautions, side effects, warnings, contraindications, and interactions that may be associated with your drug treatments. Your healthcare professional should discuss your treatment and possible side effects with you. If you would like more information, talk to your doctor or other healthcare professional. You can ask your pharmacist or doctor for information about Folllistim AQ Cartridge that is written for healthcare professionals.

For questions on information contained in this leaflet, call
1-866-836-5633
www.folllistim.com

Folllistim® and Folllistim Pen® are registered trademarks of N.V. Organon
BD Micro-Fine™ is a trademark of Becton, Dickinson and Company

R only



Manufactured for Organon USA Inc.
Roseland, NJ 07068
by Vetter Pharma-Fertigung GmbH & Co. KG
Ravensburg, Germany
and packaged by Organon (Ireland) Ltd.
Swords, Co. Dublin, Ireland