

INSTRUCTIONS FOR USE
FOLLISTIM® (Fol-lis-tim) AQ Cartridge
(follitropin beta)
injection, for subcutaneous use

Read this Instructions for Use before you start using FOLLISTIM® AQ Cartridge 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.

Important Information

- FOLLISTIM AQ Cartridge is injected subcutaneously (beneath the skin) only.
- FOLLISTIM AQ Cartridge is for single-patient-use only.
- FOLLISTIM AQ Cartridge is used with FOLLISTIM Pen (supplied separately).
- FOLLISTIM Pen is not recommended for use by the blind or visually impaired without the help of a person trained to use the injection device.
- Learn about all of the parts of the FOLLISTIM Pen (See Figure 1), FOLLISTIM AQ Cartridge (See Figure 2) and the BD Micro-Fine™ Pen Needle (See Figure 3).
- The BD Micro-Fine™ Pen Needle is for use only with the FOLLISTIM AQ Cartridge. Each needle is for 1 injection only.
- Do not add any other medicine to the FOLLISTIM AQ Cartridge.
- Be very careful when handling the needle. If you are giving an injection to another person, accidental needle sticks with used needles can cause serious infections or infections that may lead to death.

Storing FOLLISTIM AQ Cartridge

- Store unused FOLLISTIM AQ Cartridge in the refrigerator between 36°F to 46°F (2°C to 8°C) until the expiration date.
- If needed, FOLLISTIM AQ Cartridge can be stored at room temperature up to 77°F (25°C) for 3 months or until the expiration date, whichever comes first.
- After first use, store FOLLISTIM AQ Cartridge either in the refrigerator or at room temperature between 36°F to 77°F (2°C to 25°C). Throw away after 28 days, even if there is still medicine in the FOLLISTIM AQ Cartridge.
- Keep FOLLISTIM AQ Cartridge in the original carton to protect from light.
- Do not freeze.

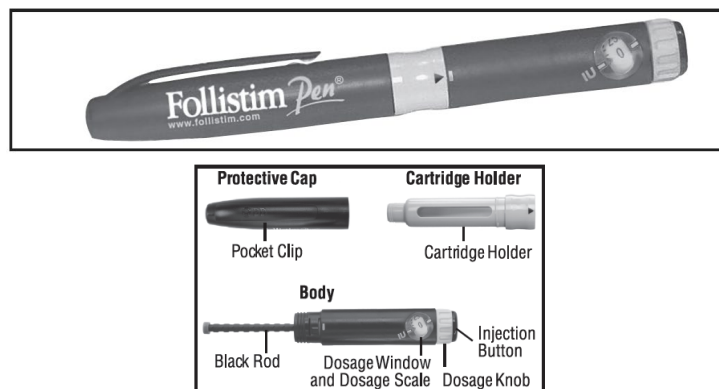


Figure 1. FOLLISTIM Pen and its Parts

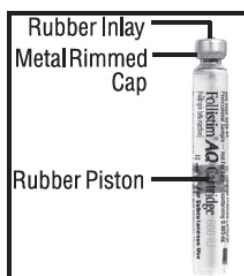


Figure 2. Parts of FOLLISTIM AQ Cartridge

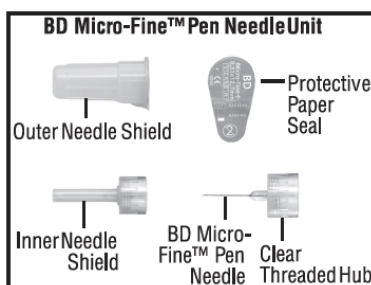


Figure 3. Parts of BD Micro-Fine Pen Needle Unit

A. Getting Ready

- Remove the FOLLISTIM AQ Cartridge out of the refrigerator.
- Injecting cold medicine can cause discomfort at the injection site. Allow the FOLLISTIM AQ Cartridge to reach room temperature before injecting.
- Check the liquid in the cartridge to make sure it is clear and colorless. **Do not use**, if the liquid is not clear and colorless or has particles in it.
- **Gather the supplies you will need for your injection. You will need:**
 - a clean dry surface
 - FOLLISTIM Pen
 - FOLLISTIM AQ Cartridge
 - BD Micro-Fine Pen Needle
 - alcohol pads
 - cotton balls or sterile gauze
 - a puncture-proof container to throw away the used cartridge and needle
- Wash your hands with soap and water and dry them before you use FOLLISTIM Pen and when you replace the cartridge.

B. Loading the FOLLISTIM Pen with the FOLLISTIM AQ Cartridge

- Hold the FOLLISTIM Pen Body firmly with one hand. With the other hand, pull the Protective Cap straight off with your other hand (See Figure 4). Put the cap aside on a clean, dry surface.

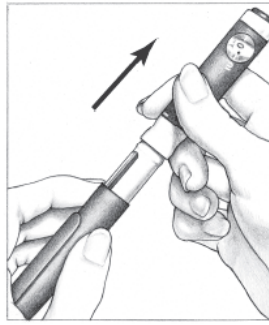


Figure 4

- Unscrew the Pen Body from the Cartridge Holder (See Figure 5). Place the Cartridge Holder and the Pen Body aside.

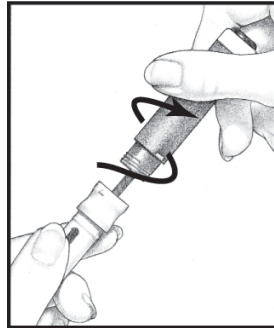


Figure 5

- Take the FOLLISTIM AQ Cartridge out of the package. Clean the rubber inlay on the cartridge with an alcohol pad. Put the FOLLISTIM AQ Cartridge into the Cartridge Holder (See Figure 6). The metal rimmed cap goes in first.

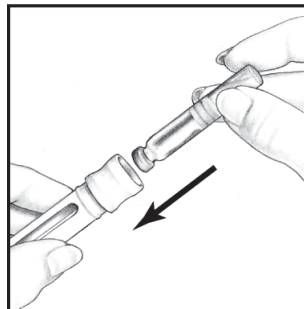


Figure 6

- Insert the Pen Body 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 (See Figure 7). 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 Pen Body.

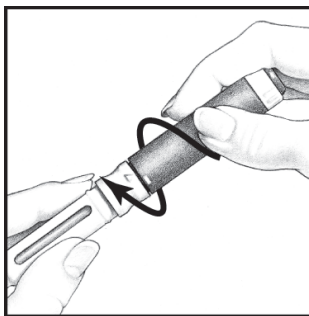


Figure 7

- Clean the open end of the Cartridge Holder with an alcohol pad (See Figure 8).

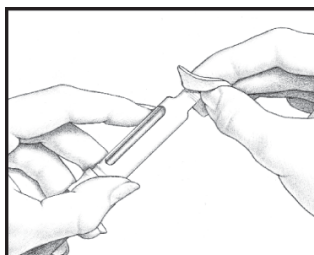


Figure 8

- Pick up a new BD Micro-Fine Pen Needle that is in its Outer Needle Shield. Peel off the protective paper seal (See Figure 9). **Do not** touch the needle. **Do not** place the open needle on any surface. **Use only the BD Micro-Fine 0.33 mm × 12.7 mm (29G) Pen Needles as supplied with the FOLLISTIM AQ Cartridge.**
- Use a new BD Micro-Fine Pen Needle with each injection. Never reuse a needle. Attach a new BD Micro-Fine Pen Needle after you make sure there is a FOLLISTIM AQ Cartridge in the Cartridge Holder.

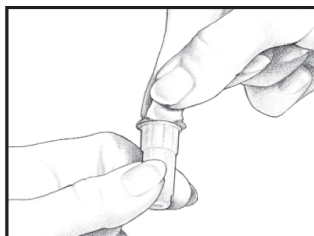


Figure 9

- 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 (See Figure 10). Place your FOLLISTIM Pen aside.

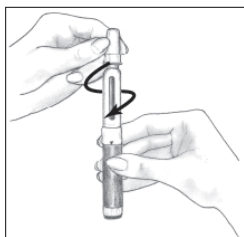


Figure 10

C. Preparing the Injection Site

- 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 Cartridge into an area that is tender, red, bruised, or hard.
- The recommended sites for injecting FOLLISTIM AQ Cartridge are:

- just below your belly button (navel) (See Figure 11)

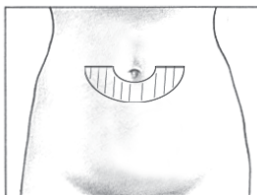


Figure 11

- the upper outer area of your thigh (See Figure 12)

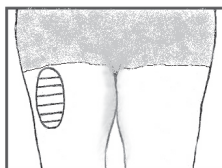


Figure 12

- Choose an injection site. Clean the skin at the injection site with an alcohol wipe. Clean about two inches around the injection site where the needle will be inserted. Do not touch the cleaned area of skin.

D. Dialing the Dose Before You Give the Injection

- Your healthcare provider 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.
- FOLLISTIM AQ Cartridge using FOLLISTIM Pen can be injected subcutaneously (beneath the skin) in prescribed doses from 50 International Units (IU) up to 450 IU, in marked 25 IU increments. The Dosage Scale on the Pen has numbers and audible clicks to help you set the correct dose.
- Hold the FOLLISTIM Pen and pull off the outer needle shield. Leave the Inner Needle Shield in place over the needle attached to the Pen (See Figure 13). Do not throw away the Outer Needle Shield, you will need it later when you throw away the needle.

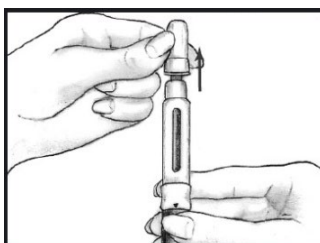


Figure 13

- Carefully remove the Inner Needle Shield and throw it away (discard) (See Figure 14). **Do not** touch the needle or let the needle touch any surface while uncapped.

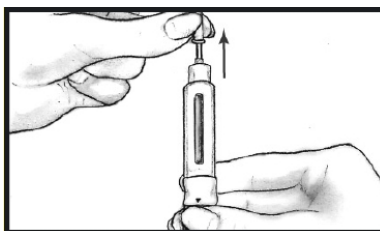


Figure 14

- Hold the FOLLISTIM 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 bubbles will not affect the amount of medicine you receive.
- With an unused cartridge loaded:

1. Dial the Dosage Knob until you hear 1 click. With the needle pointing upwards, push in the Injection Button.
2. Look for a droplet of medicine at the tip of the needle (See Figure 15). If you see the droplet, then you can dial in your dose.
3. If you do **not** see a droplet, repeat number 1 (above) until you see droplet.

You must **make sure you see a droplet** of medicine (**check the flow of medicine**) or you may **not** inject the correct dose amount.

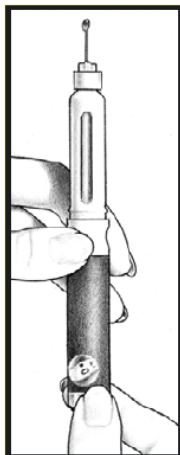


Figure 15

- With a partially used cartridge, to give yourself another dose of medicine you will need to attach a new BD Micro-Fine Pen Needle and look for a droplet forming at the tip of the needle (See Figure 15). If you see a droplet, then you can dial in your dose.

If **no** droplet:

1. Dial the Dosage Knob until you hear one click. With the needle pointing upwards, push in the Injection Button.
 2. Look for a droplet at the tip of the needle. If you see the droplet, then you can dial in your dose.
- Your FOLLISTIM AQ Cartridge should be one of the following:
 - Silver Metal Cap – 300 international units
 - Gold Metal Cap – 600 international units
 - Blue Metal Cap – 900 international units

If you do **not** have one of the cartridges above, please contact your healthcare provider.

- For doses of 50 IU up to 450 IU, turn the Dosage Knob until the correct dosage aligns with the dosage markers on each side of the Dosage Window (See Figure 16).

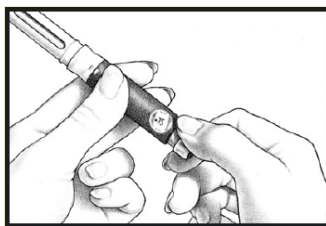


Figure 16

- If by mistake you dial past the correct dose 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 (See Figure 17). Start to dial again starting from "0" upwards. By following these directions, you will not lose any medicine from the FOLLISTIM AQ Cartridge (See "Checking the Medicine Level Remaining").

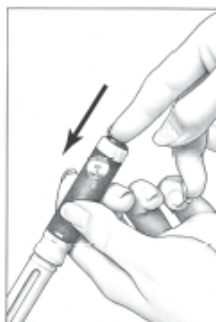


Figure 17

- If you turn the Dosage Knob backward to correct the mistake, it will not damage the FOLLISTIM Pen, but you will lose some medicine from the FOLLISTIM AQ Cartridge.
- Never dial your dose or try to correct a dialing mistake when the needle is still in your skin. You may receive an incorrect dose.
- If your prescribed dose is more than the deliverable dose of FOLLISTIM Pen or more than the amount remaining in the cartridge, you will need to give yourself more than 1 injection.

E. Giving Yourself an Injection

- Pinch a fold of skin at the cleaned injection site with one hand. **Do not** touch the cleaned area of skin.
- With the other hand hold the FOLLISTIM Pen with FOLLISTIM AQ Cartridge loaded and BD Micro-Fine Needle. Use a quick “dart-like” motion to insert the needle straight up and down (90° angle).
- Press the injection button all the way in to make sure you give yourself a full injection (See Figure 18). Wait for 5 seconds before pulling the needle out of the skin. The middle of the Dosage Window should display a dot next to the “0”.

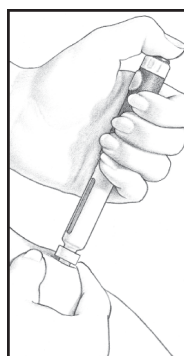


Figure 18

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 medicine 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 FOLLISTIM AQ Cartridge and a new needle and follow all the instructions up to this step (See “Giving Yourself an Injection”). Make sure you choose a different injection site to complete your prescribed dose of medicine FOLLISTIM AQ Cartridge.

- Remove the BD Micro-Fine Needle from your skin and firmly press down on the injection site with an alcohol swab. Be very careful when handling the needle. If you are giving an injection to another person, accidental needle sticks with used needles can cause serious infections or infections that may lead to death.
- Carefully follow these instructions. 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 FOLLISTIM Pen) straight into the center of the opening of the Outer Needle Shield and push down firmly (See Figure 19). Be sure the Outer Needle Shield is completely covering the entire needle.

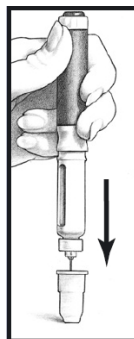


Figure 19

- Grip the Outer Needle Shield carefully and use it to unscrew the needle from the Cartridge Holder (See Figure 20).

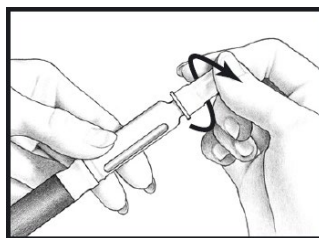


Figure 20

- Throw away the Outer Needle Shield with the used needle right away. Do not throw away in a trash can. (See “How Do I Throw Away Used Cartridges and Needles?”)
- If there is medicine left in the FOLLISTIM AQ Cartridge for more injections, put the Pen Cap back on the Pen Body and store your FOLLISTIM Pen in a safe place in the refrigerator (not in the freezer) or at room temperature. Never store the FOLLISTIM Pen with a needle attached to it.
- Unscrew the Pen Body from the Cartridge Holder with the **empty** FOLLISTIM AQ Cartridge (See Figure 21).

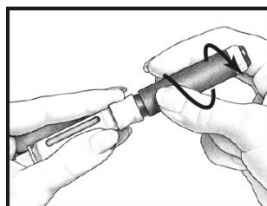


Figure 21

- Remove the empty FOLLISTIM AQ Cartridge from the Cartridge Holder (See Figure 22). Safely, throw away (dispose of) the empty FOLLISTIM AQ Cartridge right away. **Do not** put the cartridge in your household trash. (See “How Do I Throw Away Used Cartridges and Needles?”)

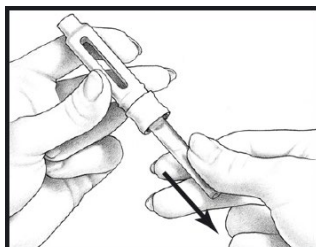


Figure 22

F. Checking the Medicine Level Remaining

For women and men:

Have your healthcare provider advise you of the number of prescribed doses that are in the full unused FOLLISTIM AQ Cartridge.

- **Do not** use the cartridge beyond the advised number of doses. Otherwise, there may not be enough medicine for your prescribed dose.

For women only:

- Keep a FOLLISTIM Pen Treatment Diary as follows:
 1. Record the FOLLISTIM AQ Cartridge content on Day 1. This will either be 300, 600 or 900 international units depending on what your healthcare provider has prescribed for you.
 2. Record the dose you have been prescribed for your injection.
 3. Subtract your Day 1 dose from the FOLLISTIM AQ Cartridge content (300, 600 or 900 international units). (See Figure 23.) This will give you the **remaining** FOLLISTIM AQ Cartridge content after the Day 1 dose is taken.
 4. Place the number determined as the content after Day 1 (See number 3) in the box as the FOLLISTIM AQ Cartridge content **available** for Day 2. (See Figure 23.)
 5. Subtract your Day 2 dose from the FOLLISTIM AQ Cartridge content you recorded in Step 4. This will give you the **remaining** FOLLISTIM AQ Cartridge content after Day 2. Record this number of units. (See Figure 23.)
 6. Repeat the steps to determine the FOLLISTIM AQ Cartridge content **available** and FOLLISTIM AQ Cartridge **remaining** for each day of use.

Day	Date	Dose Prescribed	FOLLISTIM AQ Cartridge Content Available	FOLLISTIM AQ Cartridge Content Remaining
1	month/day/year	150	600	450
2	month/day/year	150	450	300
3	month/day/year	150	300	150
4	month/day/year	150	150	0

Figure 23. Example of Treatment Diary Starting with a 600 International Unit Cartridge

If you do not know if there is not enough medicine left in the FOLLISTIM AQ Cartridge for your next prescribed dose, see section “If There is Not Enough FOLLISTIM AQ in the Cartridge”.

G. If There is Not Enough FOLLISTIM AQ in the Cartridge

1. If you realize **before** you inject that you do not have enough medicine remaining in your FOLLISTIM AQ Cartridge for your complete dose, follow either Option 1 or Option 2. **Do not** follow both.
 - Option 1:

- Dial your dose and inject the remaining medicine in the FOLLISTIM AQ Cartridge. The Dosage Knob Injection Button will not push in all the way (do not try to force down the button) and the Dosage Window number will not read "0" but will read the number of units you will need to complete your prescribed dose.
 - Write down the number of units needed to complete your dose.
 - Remove the needle and throw it away (dispose of it) properly (see “How Do I Throw Away Used Cartridges and Needles?”).
 - 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.
 - Before you replace a FOLLISTIM AQ Cartridge, be sure that a BD Micro-Fine Pen Needle is not attached to the FOLLISTIM Pen.
 - Insert a new cartridge into the FOLLISTIM Pen and attach a new BD Micro-Fine needle.
 - Dial to the number of units you have written down to complete your prescribed dose.
 - Prepare a different injection site and inject the remaining medicine to complete your dose (See “Giving Yourself an Injection”).
 - Option 2
 - Remove the FOLLISTIM AQ Cartridge.
 - **Start over** with a new FOLLISTIM AQ Cartridge and Insert into the FOLLISTIM Pen.
 - Follow the instructions for “Dialing the Dose” and “Giving Yourself an Injection.”
2. If you realize **after** you have inserted the needle at the injection site that you do not have enough medicine remaining in your FOLLISTIM AQ Cartridge for your complete dose:
- Inject the remaining content in the FOLLISTIM 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 removing the needle from your skin and gently apply pressure to the injection site with an alcohol pad.
 - Throw away (dispose of) the used needle (See “How Do I Throw Away Used Cartridges and Needles?”).
 - 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 FOLLISTIM Pen and attach a new BD Micro-Fine needle.
 - Dial to the number you have recorded to complete your prescribed dose.
 - Prepare a different injection site and inject the remaining medicine to complete your dose (See “Giving Yourself an Injection”).

H. How to Solve Problems with FOLLISTIM AQ Cartridge and FOLLISTIM Pen

If you have problems with using the FOLLISTIM AQ Cartridge and the FOLLISTIM Pen, see the following chart. If you still have problems after following the chart or if your problem is not on the chart, contact your healthcare provider.

PROBLEM	POSSIBLE CAUSES	WHAT TO DO
The Pen Body will not screw tightly into the Cartridge Holder.	Is something in the way?	Take out the FOLLISTIM Cartridge and check the Cartridge Holder to see if anything is in the way. Follow the instructions in this pamphlet to Screw the Pen Body fully onto the Cartridge Holder.
No medicine is coming out while checking the flow.	The Cartridge Holder and the Pen Body are not properly screwed together.	Remove the current needle. Carefully follow instructions (Fig. 19 and Fig. 20) to prevent accidental needle sticks. Tighten the Pen Body to the Cartridge Holder ensuring the arrow on the Cartridge Holder is pointing to the middle of the yellow alignment mark

PROBLEM	POSSIBLE CAUSES	WHAT TO DO
		<p>on the Pen Body. Attach a new needle to the Pen.</p> <p>Recheck the flow as follows:</p> <ol style="list-style-type: none"> a. Dial the Dosage Knob until you hear one click. With needle pointing upwards, push in the Injection Button. b. Look for a droplet at the tip of the needle.
	Is the FOLLISTIM Cartridge empty?	Change to a new cartridge.
	Has the needle been properly attached to the FOLLISTIM Pen?	<p>Remove needle and replace with a new one, ensuring that the needle is screwed on tightly to the Pen.</p> <p>Recheck the flow as follows:</p> <ol style="list-style-type: none"> a. Dial the Dosage Knob until you hear one click. With needle pointing upwards, push in the Injection Button. b. Look for a droplet at the tip of the needle.
You are concerned that you can turn the Dosage Knob to the next number without clicking and the Injection Button spins freely.	This is not a problem.	The system is in the reset mode. The Injection Button and Dosage Knob must be pushed all the way down to '0' to re-engage the mechanism and the correct dose can now be set. A click will be heard for each setting in the viewing window.
The Dosage Knob does not go back to '0' while you are injecting.	Is the FOLLISTIM Cartridge empty?	Change to a new cartridge.
	Is the needle blocked?	<ol style="list-style-type: none"> a. Remove the needle from the skin and dispose of safely. b. Check the Dosage Window and note how much remaining medicine to inject. c. Attach a new needle. <p>Recheck the flow as follows:</p> <ol style="list-style-type: none"> a. Dial the Dosage Knob until you hear one click. With needle pointing upwards, push in the Injection Button. b. Look for a droplet at the tip of the needle. c. Dial remaining dose.
Some of the medicine is dripping out of the needle when you withdraw it from your skin.	Did you take the needle out of your skin before waiting 5 seconds as directed in Step 15?	If this happens you should inform your doctor. To avoid this problem again, you should always wait 5 seconds after you push the Injection Button before you withdraw the needle from your skin.
The needle is left on the FOLLISTIM Pen.	Have you missed any of the instructions?	Dispose of the needle in a properly secured container as instructed by

PROBLEM	POSSIBLE CAUSES	WHAT TO DO
		your doctor. Carefully follow instructions (Fig. 19 and Fig. 20) to prevent accidental needle sticks. Change to a new FOLLISTIM Cartridge and a new needle.
After your last injection, a remaining volume may be left in the cartridge in addition to the normal quantity of medicine dispensed.	The cartridge contains extra volume for checking the medicine flow.	This is not a problem.
You cannot get the cartridge out of the FOLLISTIM Pen.	Is the needle attached?	Remove the needle from the FOLLISTIM Pen and dispose of properly. (Unscrew the Cartridge Holder from the Pen Body and take out the cartridge.)
You are not sure how much medicine is left in the cartridge, and you do not want to start an injection and then find out that there is not enough medicine.	Have you kept good records of your doses?	In case of any doubt, you should load a new, unused FOLLISTIM Cartridge into the FOLLISTIM Pen. See “If There is Not Enough FOLLISTIM AQ in the Cartridge.” To avoid this problem again, you should record your injections. (Women should use a treatment diary.)

Important: If you have a question, always mention the Lot number of your FOLLISTIM Pen as printed on the Pen Body. If you have a complaint, please do not discard any product or packaging.

For questions on information contained in this leaflet, call 1-844-674-3200.

www.follistim.com

How Do I Throw Away Used Cartridges and Needles?

- Put **your used cartridges and needles in** an FDA-cleared sharps disposal container right away after use. **Do not** throw away (dispose of) loose needles and cartridges in your household trash.
- If you do not have an FDA-cleared sharps container, you may use a household container that is:
 - made of heavy-duty plastic,
 - can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out,
 - upright and stable during use,
 - leak resistant, and
 - properly labeled to warn of hazardous waste inside the container.
- When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should throw away used cartridges and needles. For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA’s website at: <http://www.fda.gov/safesharpsdisposal>.

Do not dispose of your used sharps disposal container in your household trash unless your community guidelines permit this. **Do not** recycle your used sharps disposal container.

How Do I Care for the FOLLISTIM Pen?

1. Clean all exposed parts of the FOLLISTIM Pen with a clean, damp cloth such as a paper towel. Never wash it in water, detergent, or strong medical cleaners.
2. Handle the FOLLISTIM Pen carefully to avoid causing damage. You could damage the FOLLISTIM Pen by dropping it or handling it roughly.
3. Keep the FOLLISTIM Pen away from dust and dirt.
4. Never store the FOLLISTIM Pen with a needle attached to it. If you store the FOLLISTIM Pen with the needle attached, the medicine could leak out and there is risk of contamination.
5. If the FOLLISTIM Pen breaks or is damaged, do not try to fix it yourself. Contact your healthcare provider.
6. Do not share your FOLLISTIM Pen with another person.

Keep FOLLISTIM Pen, FOLLISTIM AQ Cartridge, any other supplies and all medicines out of the reach of children.

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 **ORGANON & Co.**,
Jersey City, NJ 07302, USA
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For patent information: www.organon.com/our-solutions/patent/

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