

## **Patient Information**

### **MENOPUR® (Men-oh-pyoor) (menotropins for injection) for subcutaneous use**

Read this Patient Information before you start using MENOPUR® (menotropins for injection) and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment.

#### **What is MENOPUR?**

MENOPUR is a prescription medicine that contains follicle stimulating hormone (FSH) and luteinizing hormone (LH). MENOPUR causes your ovaries to make multiple (more than 1) eggs as part of an Assisted Reproductive Technology (ART) cycle.

#### **Who should not use MENOPUR?**

##### **Do not use MENOPUR if you:**

- are allergic to menotropins or any of the ingredients in MENOPUR. See the end of this leaflet for a complete list of ingredients in MENOPUR.
- have ovaries that no longer make eggs (primary ovarian failure)
- are pregnant or think you may be pregnant. If MENOPUR is taken while you are pregnant, it may harm your baby.
- have problems with your thyroid gland, adrenal gland or pituitary gland that are not controlled by taking medicine.
- have a tumor in your female organs, including your ovaries, breast, or uterus that may get worse with high levels of estrogen
- have a tumor of your pituitary gland or hypothalamus
- have abnormal bleeding from your uterus or vagina and the cause is not known
- have ovarian cysts or enlarged ovaries, not due to a problem called polycystic ovary syndrome (PCOS)

#### **What should I tell my healthcare provider before using MENOPUR?**

##### **Before you use MENOPUR, tell your healthcare provider if you:**

- have been told by a healthcare provider that you are at an increased risk for blood clots (thrombosis)
- have ever had a blood clot (thrombosis), or anyone in your family has ever had a blood clot
- had twisting of your ovary (ovarian torsion)
- had or have a cyst in your ovary
- have any other medical conditions
- are breast feeding or plan to breast feed. It is not known if MENOPUR passes into your breast milk. You and your healthcare provider should decide if you will use MENOPUR or breastfeed. You should not do both.

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

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

#### **How should I use MENOPUR?**

- Read the **Instructions for Use** at the end of this Patient Information about the right way to use MENOPUR or MENOPUR mixed with BRAVELLE® (urofollitropin for injection, purified).
- Use MENOPUR exactly as your healthcare provider tells you to use it.
- Your healthcare provider will tell you how much MENOPUR to use and when to use it.

- Your healthcare provider may change your dose of MENOPUR if needed.
- If you miss a dose of MENOPUR, call your healthcare provider right away. **Do not** double the amount of MENOPUR you are using.
- You may need more than 1 vial of MENOPUR for your dose.
- MENOPUR may be mixed with BRAVELLE in the same syringe.

#### What are possible side effects of MENOPUR?

##### MENOPUR may cause serious side effects, including:

- **ovaries that are too large.** MENOPUR may cause your ovaries to be abnormally large. Symptoms of large ovaries include bloating or pain in your lower stomach (pelvic) area. If your ovaries become too large your healthcare provider may tell you that you should not have intercourse (sex) so you do not rupture an ovarian cyst.
- **ovarian hyperstimulation syndrome (OHSS).** Using MENOPUR may cause OHSS. OHSS is a serious medical condition that can happen when your ovaries produce too many eggs (overstimulated). OHSS can cause fluid to suddenly build up in the area of your stomach, chest, heart, and cause blood clots to form. OHSS may also happen after you stop using MENOPUR. Stop using MENOPUR and call your healthcare provider or go to the nearest hospital emergency room right away if you have any of the following symptoms of OHSS:
  - severe pelvic or stomach pain
  - nausea
  - vomiting
  - sudden weight gain
  - swollen stomach
  - diarrhea
  - trouble breathing
  - decreased or no urine
- **lung problems.** MENOPUR may cause serious lung problems that can sometimes lead to death including fluid in the lungs, trouble breathing, and worsening of asthma.
- **blood clots.** MENOPUR 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 lung (pulmonary embolus)
- **twisting (torsion) of your ovary.** MENOPUR may increase the chance of your ovary twisting, if you already have certain conditions such as OHSS, pregnancy, and previous abdominal surgery. Twisting of your ovary may lead to blood flow being cut off to your ovary.
- **pregnancy with and birth of multiple babies.** MENOPUR may increase your chance of having a pregnancy with more than 1 baby. Having a pregnancy and giving birth to more than 1 baby at a time increases the health risk for you and your babies. Your healthcare provider should talk to you about your chances of multiple births before you start using MENOPUR.
- **birth defects.** Babies born after ART may have an increased chance of birth defects. Your age, certain sperm problems, your genetic background, and that of your partner, and a pregnancy with more than 1 baby at a time may increase the chance that your baby may have birth defects.
- **ectopic pregnancy (pregnancy outside your womb).** MENOPUR may increase your chance of having a pregnancy that is abnormally outside of your womb. Your chance of having a pregnancy outside of your womb is increased if you also have fallopian tube problems.
- **miscarriage.** Your chance of loss of an early pregnancy may be increased if you had difficulty becoming pregnant.
- **tumors of the ovary.** If you have used medicines like MENOPUR more than 1 time to get pregnant, you may have an increased chance of having tumors in your ovaries, including cancer.

The most common side effects of MENOPUR include:

- stomach cramps, fullness or pain
- headache
- injection site swelling, heat, redness and pain

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

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

**How should I store MENOPUR?**

- Before mixing, store MENOPUR powder in the refrigerator or at room temperature between 37°F to 77°F (3°C to 25°C).
- Protect MENOPUR from light.
- MENOPUR should be used right after mixing.
- Throw away any unused MENOPUR.

**Keep MENOPUR and all medicines out of the reach of children.**

**General Information about the safe and effective use of MENOPUR.**

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

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

For more information go to [www.menopur.com](http://www.menopur.com), or call 1-888-FERRING (1-888-337-7464).

**What are the ingredients in MENOPUR?**

Active ingredient: menotropins

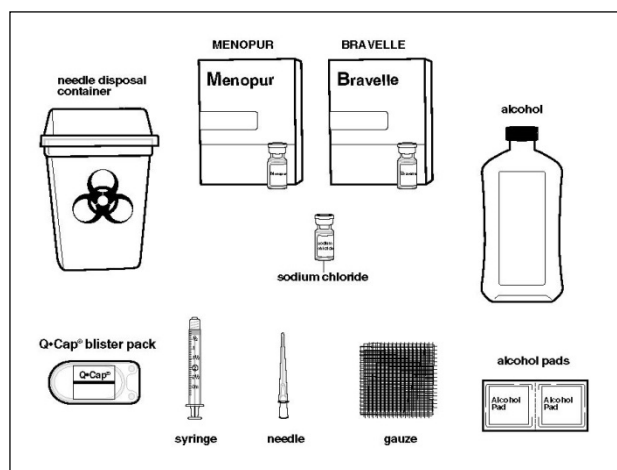
Inactive ingredients: lactose monohydrate, polysorbate, sodium phosphate buffer (sodium phosphate dibasic, heptahydrate and phosphoric acid)

**Instructions for Use**  
**MENOPUR® (Men-oh-pyoor)**  
**(menotropins for injection)**  
**for subcutaneous use**

Your healthcare provider should show you how to mix and inject **MENOPUR®** (menotropins for injection) or **MENOPUR mixed with BRAVELLE®** (urofollitropin for injection, purified) before you do it for the first time. Before using MENOPUR or MENOPUR mixed with BRAVELLE for the first time, read this **Instructions for Use** carefully. Keep this leaflet in a safe place and read it when you have questions.

**Supplies you will need to give your injection of MENOPUR or MENOPUR mixed with BRAVELLE. See Figure A.**

- a clean, flat surface to work on, like a table
- vials of MENOPUR powder (and BRAVELLE powder if you are going to mix the 2 medicines)
- 1 vial of 0.9% Sodium Chloride, USP used for mixing the medicine
- alcohol pads
- rubbing alcohol
- gauze pads
- 1 sterile syringe and 1 sterile needle with cap. Your healthcare provider should tell you which syringe and needle to use.
- the Q•Cap® (vial adapter) that comes with your medicine
- a sharps disposal container for throwing away your used needles and syringes. See “**Disposing of your used needles and syringes**” at the end of these instructions.

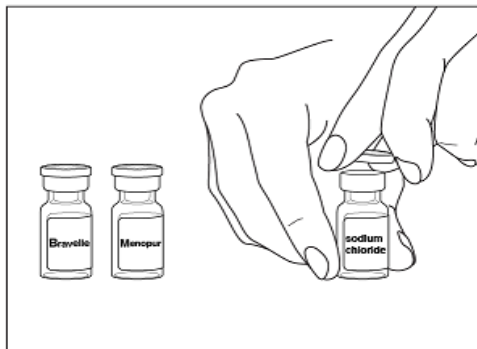


**Figure A**

**Step 1. Preparing your MENOPUR or MENOPUR mixed with BRAVELLE.**

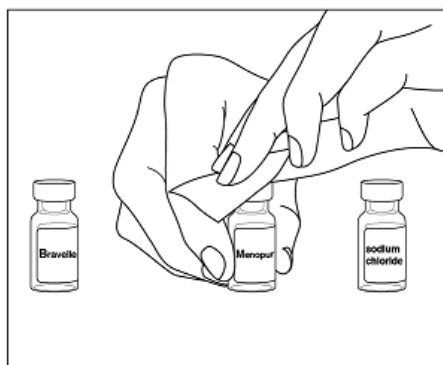
- Wash your hands well with soap and water and dry them with a clean towel.
- Place all the supplies you need on the clean surface you already prepared.
- Check the vial(s) of MENOPUR (and BRAVELLE if needed) to make sure there is powder or a pellet in the vial(s). If you do not see any powder in the vial(s) do not use the vial and call your pharmacist or healthcare provider.

- Check the 0.9% Sodium Chloride, USP vial to make sure that the liquid is clear and does not contain any particles. If you see any particles in the liquid or the liquid is discolored, do not use the vial and call your pharmacist or healthcare provider.
- Check the Q•Cap blister pack package to make sure it is intact. Do not use if the package is damaged.
- Remove the plastic cap(s) from the vial(s) of MENOPUR (and BRAVELLE if needed) and 0.9% Sodium Chloride, USP vial(s). **See Figure B.**



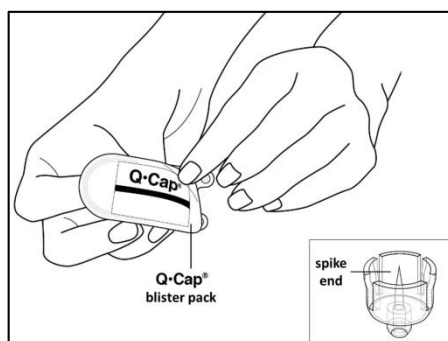
**Figure B**

- Wipe the tops of the vials with alcohol and allow them to dry. Do not touch the tops of the vials after you have wiped them. **See Figure C.**



**Figure C**

- Place the vial of 0.9% Sodium Chloride, USP on the table.
- Open the Q•Cap blister pack by peeling back the lidding (**See Figure D**). Do not take the Q•Cap out of the blister pack at this time. **Do not** touch the spike or connector (luer) ends of the Q•Cap.

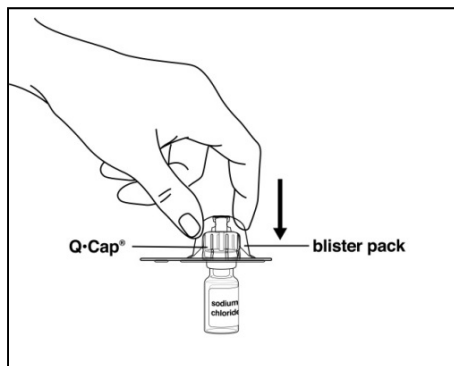


**Figure D**

- Hold the 0.9% Sodium Chloride, USP vial in 1 hand. With your other hand, hold the sides of the Q•Cap blister pack, turn the Q•Cap blister pack over, and place it on top of the vial. Push the Q•Cap straight

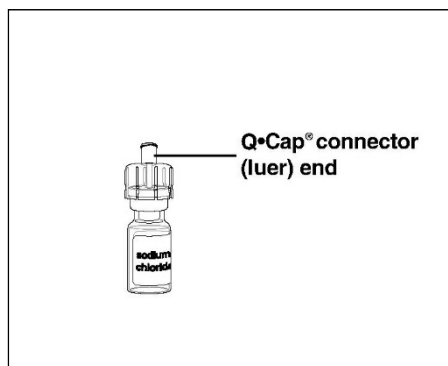
down into the rubber stopper of the vial until the Q•Cap spike pierces the top of the vial and snaps into place. **See Figure E.**

- **Do not** use the Q•Cap if it falls out of the blister pack. Throw it away and get a new one.



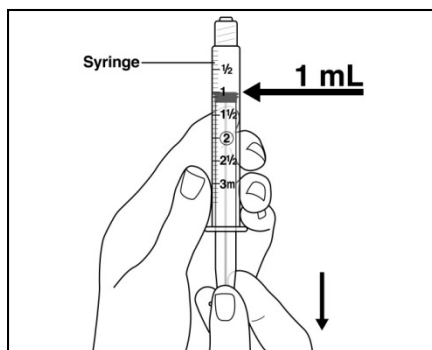
**Figure E**

- Remove the blister pack and throw it away in your household trash. Do not touch the connector end (luer) of the Q•Cap. **See Figure F.**



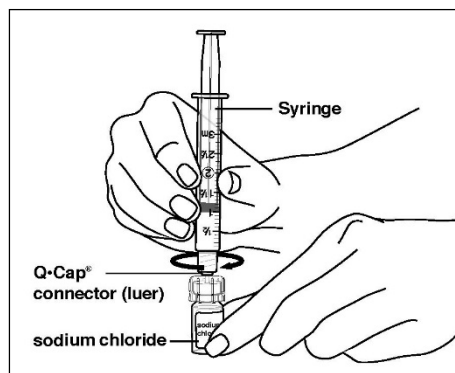
**Figure F**

- Take the syringe and pull down on the syringe plunger rod until you have reached the line that corresponds with the amount of 0.9% Sodium Chloride, USP that your healthcare provider told you to use (typically 1 mL). Air is just being drawn into the syringe at this step. **See Figure G.**  
**NOTE:** The usual amount of 0.9% Sodium Chloride, USP used to mix your MENOPUR is 1 mL.



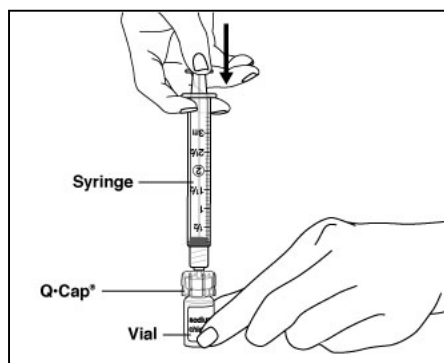
**Figure G**

- Be very careful not to touch the syringe plunger during this step.
- Place the tip of the syringe into the connector end (luer) of the Q•Cap then twist the syringe clockwise until it is tight. Be careful not to overtighten the syringe. **See Figure H.**



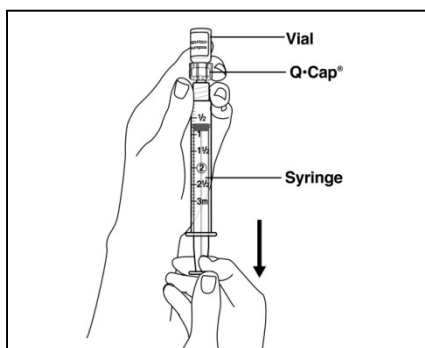
**Figure H**

- Slowly push down on the syringe plunger to push the air from the syringe into the vial. **See Figure I.**



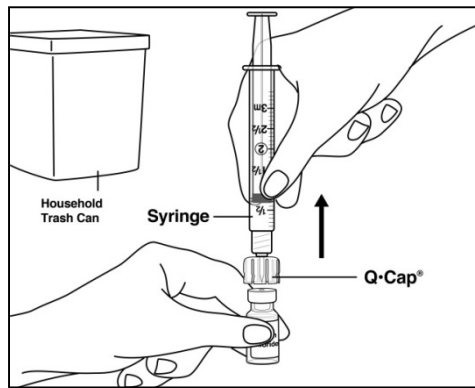
**Figure I**

- Keeping the syringe and Q•Cap together, turn the vial upside down and pull down on the syringe plunger to withdraw the right amount of 0.9% Sodium Chloride, USP from the vial. Your healthcare provider should tell you the right amount of 0.9% Sodium Chloride, USP to use. **See Figure J.**



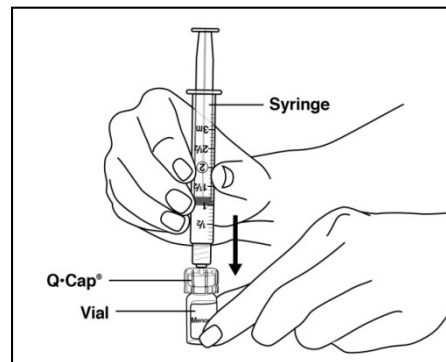
**Figure J**

- Separate the Q•Cap and syringe from the vial by pulling up on the syringe barrel. Do not pull the plunger to remove the Q•Cap. Throw away 0.9% Sodium Chloride, USP vial in your household trash. **See Figure K.**



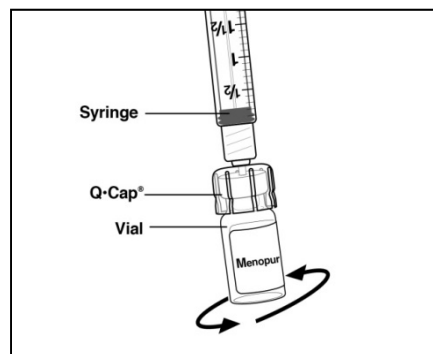
**Figure K**

- Hold the vial of MENOPUR powder in 1 hand. With your other hand, hold the sides of the syringe with the Q•Cap attached and place the tip of the Q•Cap over the top of the vial. Push the tip of the Q•Cap into the rubber stopper on the top of the vial until it stops and snaps into place. Be careful not to push down on the syringe plunger during this step. **See Figure L.** You may see the powder dissolve as the Q•Cap snaps into place, but continue with the steps listed below.



**Figure L**

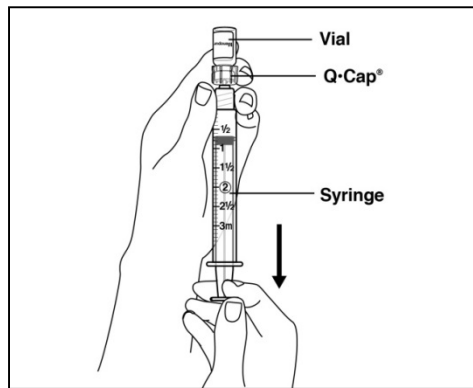
- Slowly push down on the syringe plunger to push the 0.9% Sodium Chloride, USP into the vial with the MENOPUR powder in it. The entire amount of the 0.9% Sodium Chloride, USP in the syringe should be added. Gently swirl the vial until the MENOPUR powder is completely dissolved. **Do not shake** the vial as this will cause bubbles. **See Figure M.**



**Figure M**

- As soon as the powdered medicine has completely dissolved, push the plunger down to empty any remaining air from the syringe, then turn the vial upside down and slowly pull down on the plunger to withdraw all of the MENOPUR into the syringe. **See Figure N.**
  - Be careful not to pull the plunger stopper all the way out of the syringe barrel.





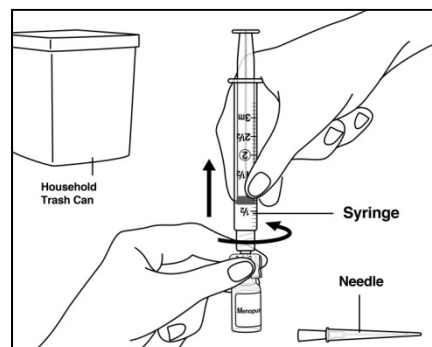
**Figure N**

**If your healthcare provider tells you to use more than 1 vial of MENOPUR or tells you to mix your MENOPUR with BRAVELLE in the same syringe:**

- Mix your first vial of MENOPUR powder or BRAVELLE powder with 0.9% Sodium Chloride, USP. **Do not** inject your dose yet.
- Use the liquid in the syringe you have just mixed to mix the next vial of MENOPUR or BRAVELLE. **See Figures K through M.**
- You can use the liquid in the syringe to mix up to 5 more vials of medicine.
- Your healthcare provider will tell you how many vials of MENOPUR and BRAVELLE to use.

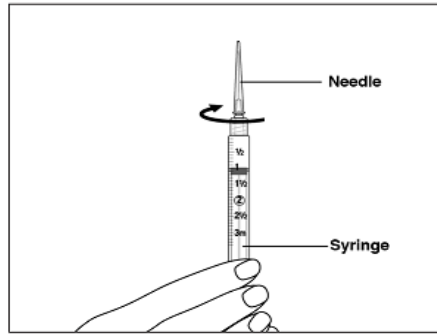
**Step 2. Removing the Q•Cap and adding your needle for injection.**

- When you have finished mixing the last vial needed for your injection and have withdrawn all the medicine into the syringe, remove the syringe from the Q•Cap by twisting the syringe counter-clockwise while holding the Q•Cap steady. **See Figure O.** Throw away the Q•Cap with the attached vial into your household trash.



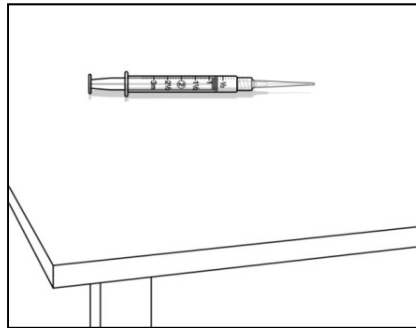
**Figure O**

- You are now ready to attach the needle to the syringe for your injection.  
**Your healthcare provider will tell you what needle you should use for your injection.**
- While holding the syringe with the syringe tip pointing up, place the needle on the top of the syringe. Gently push down on the needle and twist the needle onto the syringe in a clockwise direction until it is tight. **See Figure P.**



**Figure P**

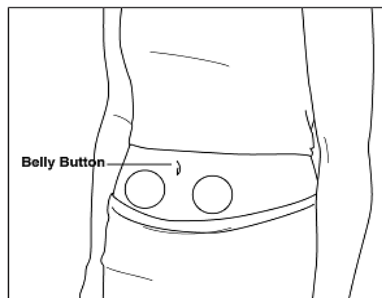
- **Do not** remove the needle cap until you are ready for your injection. (See Step 4)
  - Carefully set the syringe with the needle down on the table. See Figure Q.



**Figure Q**

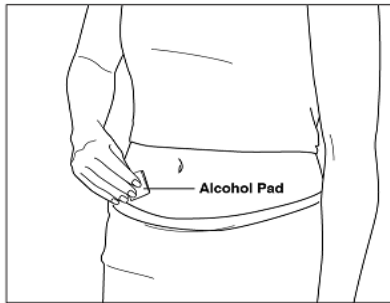
**Step 3. Prepare Injection site for MENOPUR or MENOPUR mixed with BRAVELLE.**

- Select a site to inject MENOPUR or MENOPUR mixed with BRAVELLE on your stomach area (abdomen).
  - Pick a site on your lower abdomen, 1-2 inches below the navel, alternating between left and right sides.
  - Each day, inject in a different site to help reduce soreness and skin problems. For example, on day 1, inject yourself on the right side of your abdomen. The next day, inject yourself on the left side of your abdomen. Changing your injection sites every day will help reduce soreness and skin problems. See Figure R.



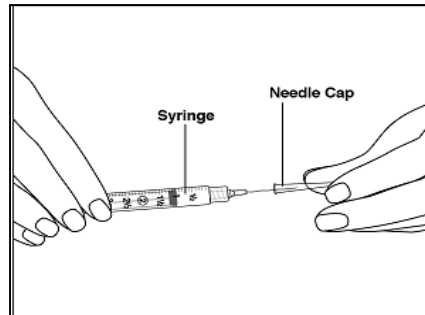
**Figure R**

- Clean your injection site with an alcohol pad. Let the alcohol dry. See Figure S.



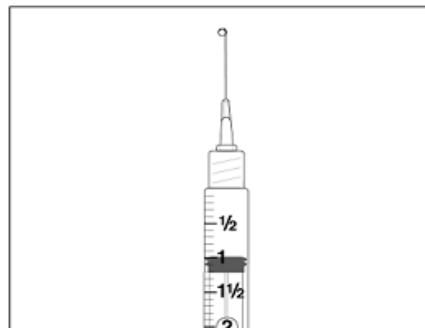
**Figure S**

- Carefully remove the needle cap from the syringe. **See Figure T.**



**Figure T**

- Hold the syringe with the needle pointing straight up. Pull down slightly on the plunger and tap the barrel of the syringe so that any air bubbles rise to the top. Slowly press the plunger up until all the air is out of the syringe and a small drop of liquid is seen at the tip of the needle. **See Figure U.**



**Figure U**

- Tap the syringe to remove the small drop of liquid at the tip of the needle. **Do not** let the needle touch anything to keep it sterile. **See Figure V.**

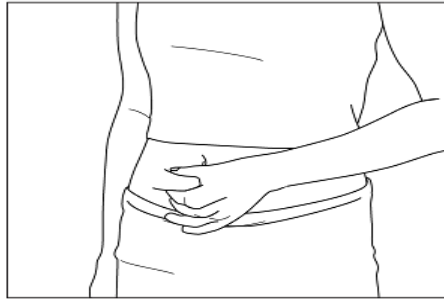


**Figure V**

- The medicine is now ready for you to inject. **See Figure V.**

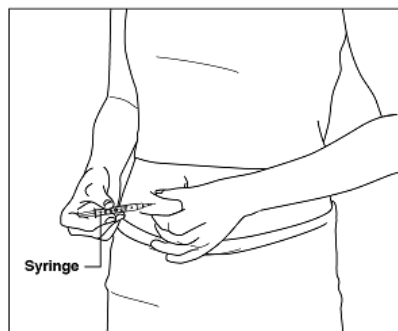
#### Step 4: Injection

- Hold the syringe in 1 hand. Use your other hand to gently pinch a fold of cleaned skin where you will insert your needle. Hold the skin between your thumb and index finger. **See Figure W.**



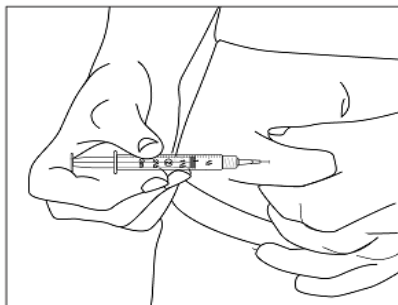
**Figure W**

- Hold your syringe at a right angle to your skin. Quickly insert the needle all the way into your skin fold. **See Figure X.**



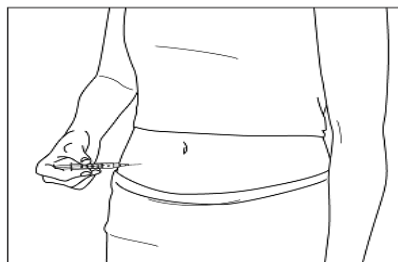
**Figure X**

- Push down the plunger of the syringe with a steady motion. Keep pushing until all the fluid is injected into your skin. **See Figure Y.**



**Figure Y**

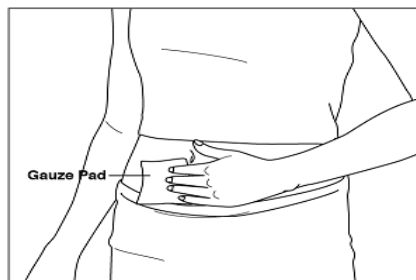
- Let go of your skin fold and pull the needle straight out of your skin. **See Figure Z.**



**Figure Z**

### Step 5. After your injection.

- If there is any bleeding at your injection site, place a gauze pad over your injection site. Apply gentle pressure to stop the bleeding. Do not rub the site. **See Figure AA.**



**Figure AA**

- If your injection site becomes sore or red, you may put ice on your injection site for 1 minute and then take it off for 3 minutes. If needed, you may repeat this 3 or 4 times.

### Step 6. Disposing of your used needles and syringes.

- Put your used needles and syringes in a FDA-cleared sharps disposal container right away after use. **Do not throw away loose needles and syringes in your household trash.**
- If you do not have a FDA-cleared sharps disposal container, you may use a household container that:
  - is made of a heavy-duty plastic,
  - can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out,
  - remains upright and stable during use,
  - is leak-resistant, and
  - is 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 needles and syringes. 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.

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

MANUFACTURED FOR:



FERRING PHARMACEUTICALS INC.  
PARSIPPANY, NJ 07054

8109000033  
Rev: 05/2018