

Instructions for Use
MENOPUR (Men-oh-pyoor)
(menotropins powder for solution for injection)
(For subcutaneous use)

How should I store MENOPUR?

- Before mixing, store MENOPUR powder in the refrigerator between 36°F to 46°F (2°C to 8°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.

Your study doctor or nurse should show you how to mix and inject **MENOPUR** (menotropins powder for solution for injection) before you do it for the first time. Before using MENOPUR for the first time, read these **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:

- a clean, flat surface to work on, like a table
- vials of MENOPUR powder
- 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 study doctor or nurse will provide the syringe and needle for your use.
- the Q•Cap® (vial adapter) that comes with your study drug
- sharps disposal container for throwing away your used needles and syringes that has been provided at your last study visit by your study coordinator or nurse. See “**Disposing of your used needles and syringes**” at the end of these instructions.

Step 1. Preparing your MENOPUR

- 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 to make sure there is powder in the vial(s). If you do not see any powder in the vial(s) do not use the vial and call the study doctor or nurse.
- 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 the study doctor or nurse.
- 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 0.9% Sodium Chloride, USP vial(s). **See Figure A.**

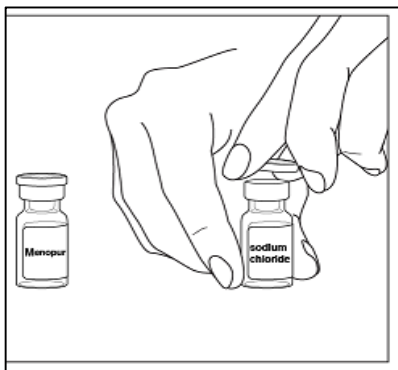


Figure A

- 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 B.**



Figure B

- 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 C**). 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.

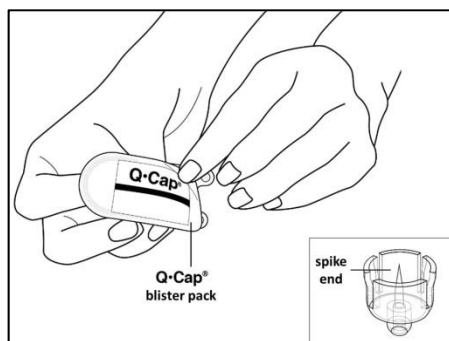


Figure C

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

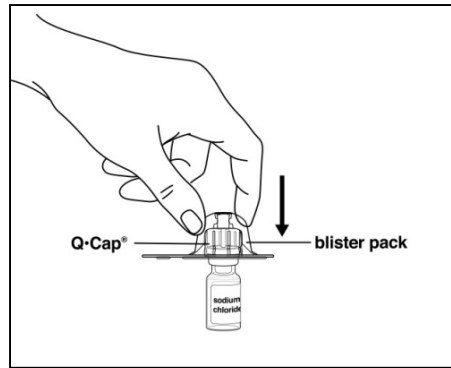


Figure D

- 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 E.**

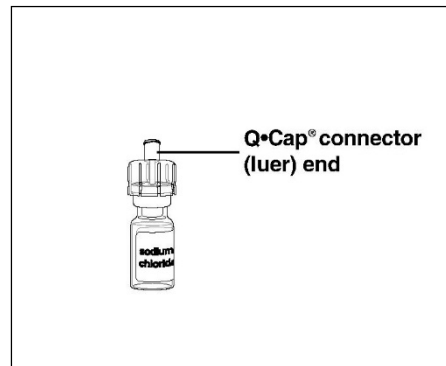


Figure E

- Take the syringe and pull down on the syringe plunger rod until you have withdrawn the amount of 0.9% Sodium Chloride, USP from the vial that your study doctor told you to use. Air is just being drawn into the syringe at this step. **See Figure F.**

NOTE: The usual amount of 0.9% Sodium Chloride, USP used to mix your MENOPUR is 1 mL.

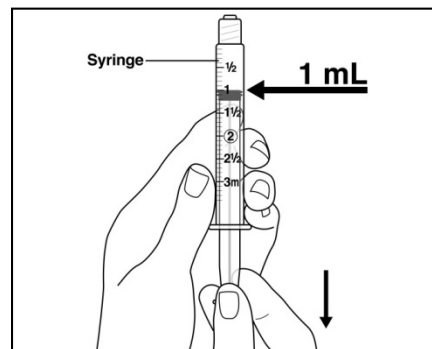


Figure F

- 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 G.**

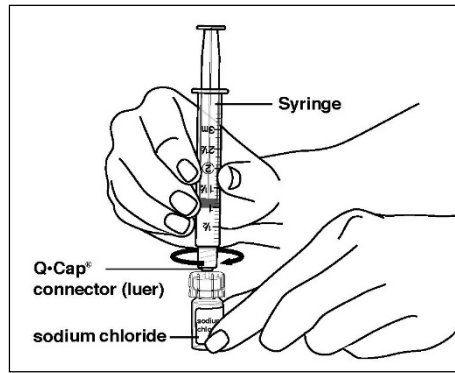


Figure G

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

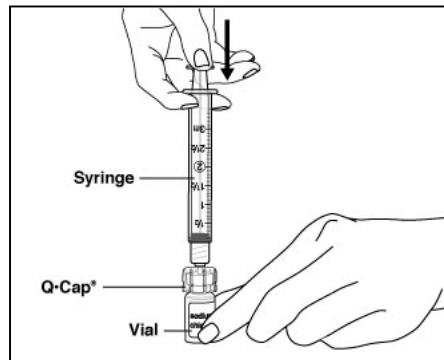


Figure H

- 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 study doctor or nurse should tell you the right amount of 0.9% Sodium Chloride, USP to use. **See Figure I.**

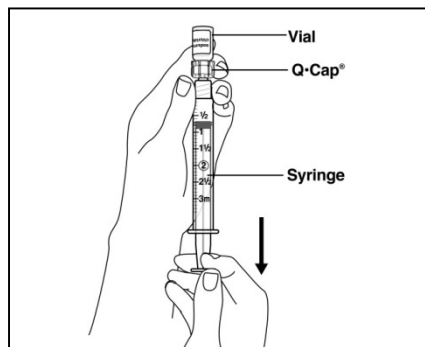


Figure I

- 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 J.**

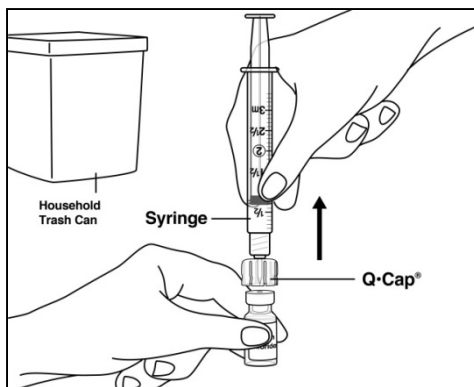


Figure J

- Hold the vial of MENOPUR powder in one 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 K.** You may see the powder dissolve as the Q•Cap snaps into place, but continue with the steps listed below.

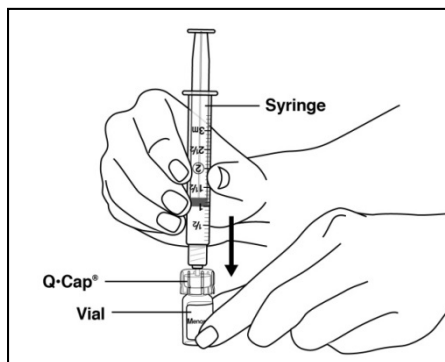


Figure K

- 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 L.**

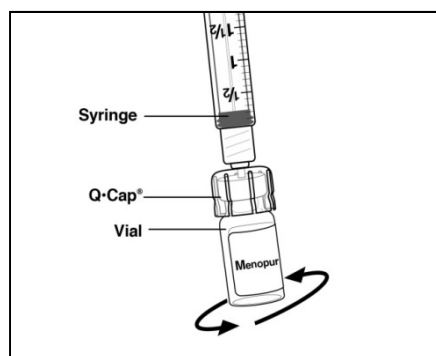


Figure L

- 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 M.**
- Be careful not to pull the plunger stopper all the way out of the syringe barrel.

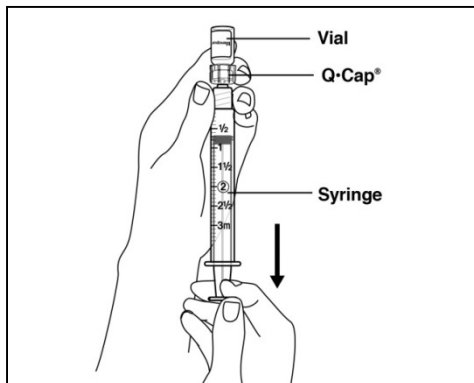


Figure M

If your study doctor or nurse tells you to use more than 1 vial of MENOPUR:

- Mix your first vial of MENOPUR 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 **See Figures J through L.**
- You can use the liquid in the syringe to mix up to 5 more vials of medicine.
- Your study doctor or nurse will tell you how many vials of MENOPUR 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 N.** Throw away the Q•Cap with the attached vial into your household trash.

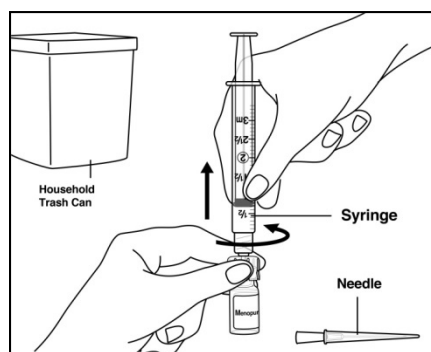


Figure N

- You are now ready to attach the needle to the syringe for your injection.
Only use the syringes and needles that have been provided to you.
- 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 O.**

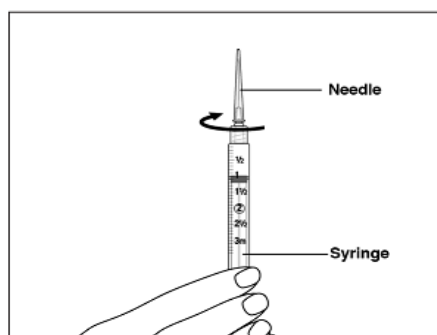


Figure O

- **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 P**

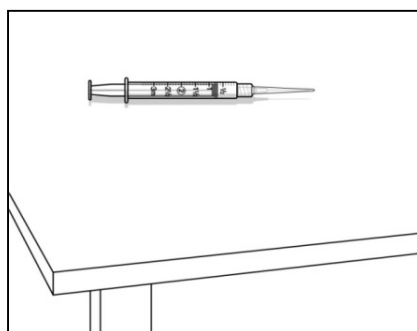


Figure P

Step 3. Prepare Injection site for MENOPUR

- Select a site to inject MENOPUR on your stomach area (abdomen).
 - Pick a site on the lower, RIGHT side of your abdomen, 1-2 inches below the navel.
 - Each day, inject in a different area on the right side of your abdomen to help reduce soreness and skin problems. Changing your injection sites every day will help reduce soreness and skin problems. See **Figure Q**.



Figure Q

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



Figure R

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

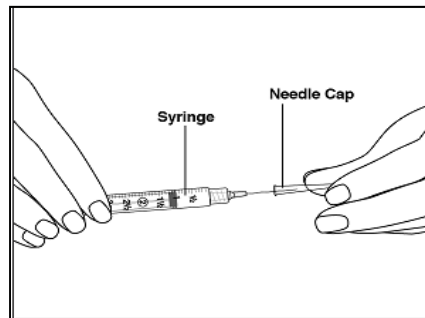


Figure S

- 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 T.**

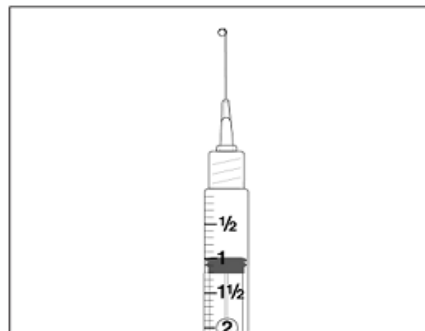


Figure T

- 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 U.**



Figure U

- The medicine is now ready for you to inject.

Step 4: Injection

- Hold the syringe in one 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 V.**

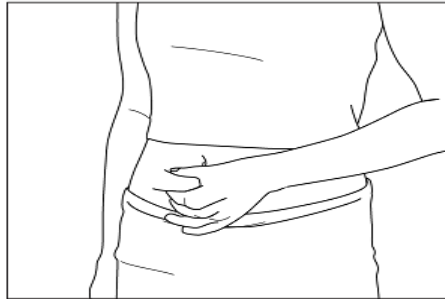


Figure V

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

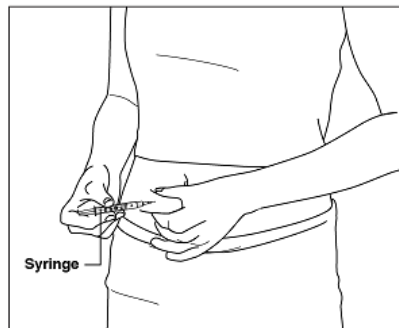


Figure W

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

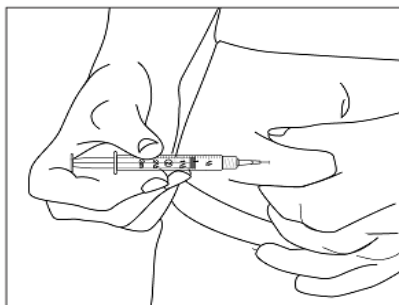


Figure X

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

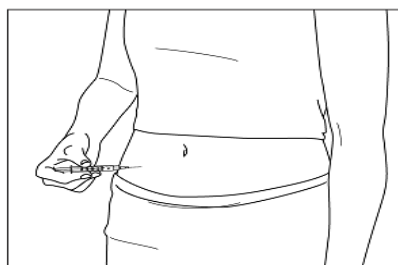


Figure Y

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 Z.**

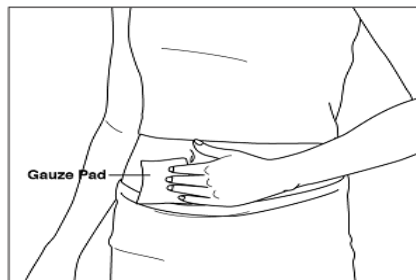


Figure Z

- 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 the sharps disposal container provided by the study doctor or nurse right away after use. **Do not throw away loose needles and syringes in your household trash.**
- 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 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 throw away your used sharps disposal container in your household trash unless your community guidelines permit this. Do not recycle your used disposal container