

Menopur[®] 75 IU

(menotropins for injection, USP)

Patient Information

Read the Patient Information that comes with Menopur[®] before you start using it and each time you get a refill. There may be new information. This leaflet does not take the place of talking to your doctor about your medical condition or your treatment.

What is Menopur[®]?

Menopur[®] is a medicine that contains the hormones follicle stimulating hormone and luteinizing hormone. These hormones stimulate healthy ovaries to make eggs. Menopur[®] is given by injection. You should use Menopur[®] as your doctor says.

Menopur[®] is used for:

- Women who are going to have in vitro fertilization and need to make many eggs.

Before using Menopur[®] you will have a health checkup. This will help your doctor learn more about your medical condition. Your doctor may prescribe Menopur[®] and you may also be asked to take other medicines. Many women take more than one medicine as part of a pregnancy plan.

Who should not use Menopur[®]?

Do not use Menopur[®] if you:

- Have ovaries that are not able to make eggs even with help.
- Are pregnant or think you may be pregnant.
- Have problems with your thyroid gland or adrenal gland that are not controlled by taking medicine.
- Have cancer in your female organs (ovaries, breasts, uterus).
- Have a tumor of your pituitary gland or other tumor in your brain.
- Have heavy or irregular vaginal bleeding from and the cause is not known.

- Have ovarian cysts or enlarged ovaries, not due to a condition known as polycystic ovary syndrome (PCOS).

What should I tell my doctor before using Menopur®?

Tell your doctor about any other medicines you are taking. This includes any prescription or non-prescription medicine, vitamins or herbal supplements.

Tell your doctor if you are breast feeding. It is not known if Menopur® passes into your milk.

How should I use Menopur®?

- Use Menopur® just as your doctor says. You will be given the amount that is right for you. Do not change the amount unless your doctor tells you to. Your doctor will tell you how much Menopur® to use each day, and how many days to take it.
- If you use too much or too little Menopur®, call your doctor right away.
- If you forget to use Menopur®, call your doctor right away. Do not double the amount of Menopur® that you are taking.
- Do not give Menopur® to anyone else. That includes other women who are having trouble getting pregnant.

What are possible side effects with Menopur®?

Menopur® may cause serious side effects including:

- Menopur® sometimes stimulates the ovaries too much. This is called ovarian hyperstimulation syndrome (OHSS) and can be a serious medical problem. OHSS may cause pelvic pain or breathing problems. It may also make you urinate less. In rare cases, patients with this problem have had serious lung problems. This includes fluid in the lungs, trouble breathing, and worsening of asthma.
- Blood clots and strokes

Call your doctor or get medical help right away if you have:

- severe pelvic pain
- nausea
- vomiting
- diarrhea
- sudden weight gain
- trouble breathing
- decreased or no urination

Menopur[®] may cause you to be pregnant with twins, or more than two babies at the same time. Your doctor will talk to you about this.

The most common with Menopur[®] are headache, stomach pain, and upset stomach. Sometimes there is a reaction at the spot where you give yourself the injection. This can include bruising, pain, or redness.

These are not all the side effects of Menopur[®]. Tell your doctor about any side effects or other symptoms you have, or any physical changes.

Step-by-Step Instructions for Using Menopur[®]

Make sure your doctor and/or nurse has taught you about mixing and injecting Menopur[®] before you do it yourself. Your doctor will decide on the dose that is best for you. This dose may be increased or decreased as your treatment goes on. Do not change the dose of Menopur[®] until your doctor tells you to.

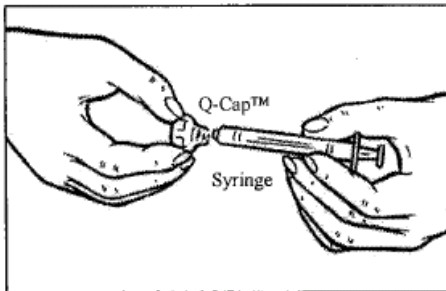
Before using Menopur[®] for the first time, read these instructions carefully. Please keep this leaflet in a safe place and refer to it when questions arise.

1. Before you start

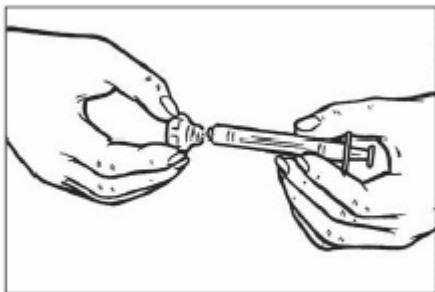
- Wash your hands well with soap. Use a soap that kills bacteria. Dry your hands with a clean towel.
- Use alcohol to clean the surface you will be working on. Lay out all the things you will need.
- Have these supplies ready as you start to prepare Menopur[®]:
 - The vial(s) of Menopur[®] powder and of Sodium Chloride 0.9% (sterile diluent) used for mixing the medicine.
 - Alcohol pads, rubbing alcohol, and gauze wipes.
 - A sterile syringe and needle.
 - Q-Cap[™] (only for exclusive use with Ferring fertility products) that is packaged with your medicine.

A “sharps container” or a large jar for getting rid of needles after you are done with them. The jar should be made from hard plastic or metal. Make sure it has a lid. You can also put used syringes or empty bottles of medicine in the jar.

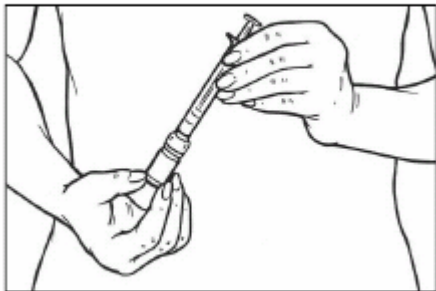
2. Preparing your Menopur® and filling the syringe



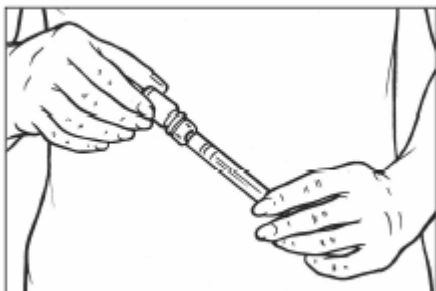
- Remove the syringe from the wrapper. If there is a capped needle on the syringe, remove the needle by twisting it counterclockwise (to the left). Open one Q-Cap™ by peeling back the label and set the blister pouch with the Q-Cap aside. Do not take the Q-Cap out of the pouch at this time. Do not touch the ends of the Q-Cap.
- Remove the plastic caps from the vials of Menopur® (menotropins for injection, USP) powder and sterile diluent.
- 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.
- Place the sterile diluent vial (Sodium Chloride 0.9%) on the counter. Remove the Q-Cap™ from the blister pouch by grasping its side. Carefully twist the syringe onto the luer end (connector) of the Q-Cap until you feel a slight resistance. Do not touch the spike at the end of the Q-Cap.



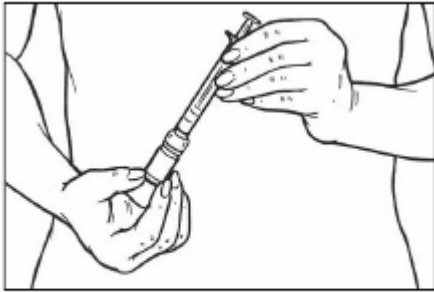
- Hold the syringe and place the spike end of the Q-Cap over the top of the sterile diluent vial. Push the tip of the Q-Cap into the rubber stopper of the vial until you feel a slight resistance. Be careful not to push down on the syringe plunger during this step.



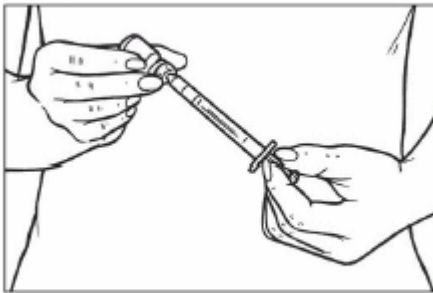
- Withdraw the syringe plunger to the volume of diluent that is to be removed from the vial. This is normally 1ml, but be sure to follow your doctor's instructions on the amount of diluent to use.



- Push the syringe plunger down to transfer the air from the syringe into the vial. Keeping the syringe and Q-Cap together, turn the vial upside down and pull back on the syringe plunger to withdraw from the vial the amount of sterile diluent specified by your doctor.
- Place the vial on the counter. Remove the Q-Cap and syringe from the vial by pulling up on the syringe barrel. Discard the diluent vial.
- Hold the Menopur[®] vial in one hand. Grasp the sides of the syringe with your other hand 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 of the vial until you feel a slight resistance. Be very careful not to push down on the syringe plunger during this step.



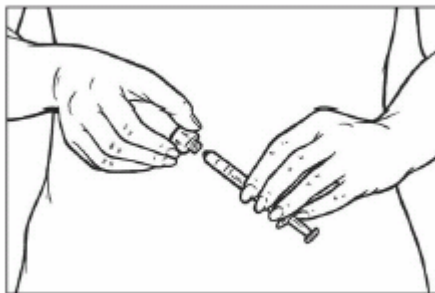
- Slowly inject the sterile diluent into the vial containing Menopur[®] powder. Gently swirl until the Menopur[®] powder is completely dissolved. Do not shake the vial as this will cause bubbles.
- As soon as the powder has completely dissolved, turn the vial upside down and withdraw all of the Menopur[®] into the syringe.



Note to patients who need multiple vials: Some patients need to use more than 1 vial of Menopur[®]. If your doctor tells you to do this, prepare the first vial of Menopur[®] with the sterile diluent. (Follow Steps 1 to 12.) Then use the liquid in the syringe to mix up to 5 more vials of medicine. Your doctor will tell you how many vials of Menopur[®] to use.

3. Removing the Q-Cap and adding the subcutaneous needle for injection

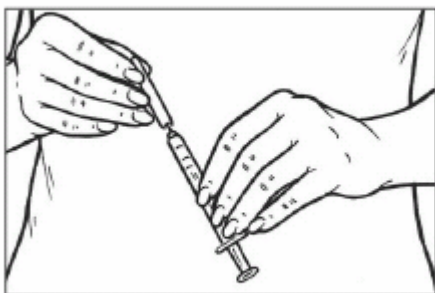
- When you have finished reconstituting the last vial necessary for your injection and have withdrawn all the medicine into the syringe, twist the syringe counterclockwise while holding the Q-Cap steady to remove the syringe from the Q-Cap. Discard the Q-Cap with the attached medicine vial.



- You are now ready to attach the injection needle to the syringe for your injection.

Note: Please follow your doctor's instructions on which needle to use.

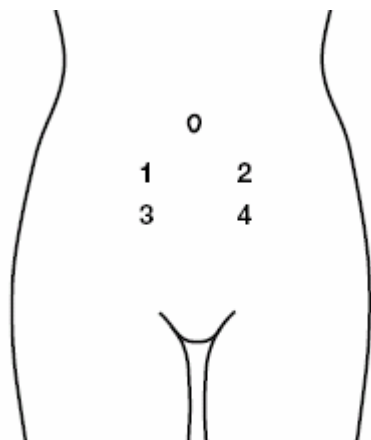
- While holding the syringe pointing upward, twist the needle clockwise (to the right) onto the syringe.



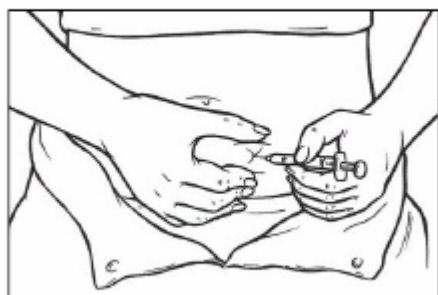
- Hold the syringe straight up. Draw back slightly on the plunger and tap the syringe so that any air bubbles rise to the top. Slowly press the plunger until all the air is out of the syringe and a small drop of solution forms at the tip of the needle.
- Tap the syringe to remove the drop of solution at the tip of the needle.
- Carefully recap the needle to keep it sterile. The medicine is now ready for injection.

4. Injecting Menopur[®]

- You should inject Menopur[®] into the skin on your stomach area (abdomen). Pick a spot a few inches below your belly button, to the left or right. Each day, inject at a different spot to help reduce soreness. See the diagram below. For example, on day 1 you could inject yourself at spot 1. The next day, you would use another spot, for example spot 2, and so on. Rotating the injection spots like this will help prevent soreness.



- Carefully clean the injection spot with an alcohol pad. Allow the spot to air- dry.
- Remove the needle cap from the syringe.
- Hold the syringe in one hand. Use your other hand to gently grasp a fold of skin for your injection. Hold the skin between your thumb and index finger.
- Hold the syringe at a right angle to the skin, like a dart. Quickly insert the needle all the way into the skin fold.



- Push the plunger of the syringe down with a steady motion. Keep pushing until all the fluid is injected into the skin.
- Release the skin fold and pull the needle straight out.

5. Disposing of the syringe and needle

- Put the cap back on the needle. Place the needle and syringe in the large jar for used supplies.
- Get rid of any opened sterile diluent or medicine still left in the vial. Used vials can be put in the large jar.
- After your treatment plan is over, be sure to get rid of the sharps container or large jar. Ask your doctor about the best way to do this.

6. After the injection

- If there is any bleeding, place a small piece of gauze over the injection spot. Apply gentle pressure to stop the bleeding.
- If the injection spot becomes sore, put some ice on it. Keep the ice on the spot for a minute or so, then remove it. Do this 3 or 4 times.

How should I store Menopur[®]?

- Store Menopur[®] in the refrigerator at 36 ° to 46 ° F (2 ° to 8 ° C), or at room temperature, 68 ° to 77 ° F (20 ° to 25 ° C). Do not freeze. Protect your medicine from light.
- Use Menopur[®] right away after mixing it with sterile saline.
- **Keep Menopur[®] and all medicines out of the reach of children.**

General information about Menopur[®]

Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets.

- **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.**
- **If you use too much Menopur[®], call your doctor right away.**

This leaflet summarizes the most important information about Menopur[®]. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about Menopur[®] that is written for health professionals. **You can also call 1- 888- FERRING.**

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/s/

Daniel A. Shames
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