6314-02

**PRODUCT INFORMATION**
# MENOPUR®
(menotropins for injection, USP)
**FOR SUBCUTANEOUS INJECTION**

## DESCRIPTION
Menopur® (menotropins for injection, USP) is a preparation of gonadotropins, extracted from the urine of postmenopausal women, which has undergone additional steps for purification. Each vial of Menopur® contains 75 International Units (IU) of follicle-stimulating hormone (FSH) activity and 75 IU of luteinizing hormone (LH) activity, plus 21 mg lactose monohydrate and 0.005 mg Polysorbate 20 and Sodium Phosphate Buffer (Sodium Phosphate Dibasic, Heptahydrate and Phosphoric Acid) in a sterile, lyophilized form intended for reconstitution with sterile 0.9% Sodium Chloride Injection, USP. Menopur® is administered by subcutaneous (SC) injection.

The biological activity of Menopur® is determined using the USP bioassays for FSH (ovarian weight gain assay in female rats) and LH (seminal vesicle weight gain assay in male rats), modified to increase the accuracy and reproducibility of these assays. The FSH and LH activity assays are standardized using the Fourth International Standard for Urinary FSH and Urinary LH, November 2000, by the Expert Committee on Biological Standardization of the World Health Organization (WHO ECBS). Human Chorionic Gonadotropin (hCG) is detected in Menopur®.

Both FSH and LH are glycoproteins that are acidic and water soluble.
Therapeutic class: Infertility.

## CLINICAL PHARMACOLOGY
Menopur®, administered for 7 to 20 days, produces ovarian follicular growth and maturation in women who do not have primary ovarian failure. In order to produce final follicular maturation and ovulation in the absence of an endogenous LH surge, hCG must be administered following Menopur® treatment, at a time when patient monitoring indicates sufficient follicular development has occurred.

## PHARMACOKINETICS
Two open-label, randomized, controlled trials were conducted to assess the pharmacokinetics of Menopur®. Study 2003-02 compared single doses of SC administration of the US and European (EU) formulations of Menopur® in 57 healthy, pre-menopausal females who had undergone pituitary suppression. The study established that the two formulations are bioequivalent. Study 2000-03 assessed single and multiple doses of Menopur® administered SC and IM in a 3 phase cross-over design in 33 healthy, pre-menopausal females who had undergone pituitary suppression. The primary pharmacokinetic endpoints were FSH AUC and $C_{max}$ values. The results are summarized in Table 1.

**Table 1: Mean (±SD) FSH Pharmacokinetic Parameters Following Menopur® Administration (Study 2000-03)**

| PK Parameters | Single Dose (225 IU) | | Multiple Dose (225 IU x 1 day then 150 IU x 6 days | |
|---|---|---|---|---|
| | SC | IM | SC | IM |
| $C_{max}$† (mIU/mL) | 8.5 (2.5) | 7.8 (2.4) | 15.0 (3.6) | 12.5 (2.3) |
| $T_{max}$ (hr) | 17.9 (5.8) | 27.5 (25.4) | 8.0 (3.0) | 9.0 (7.0) |
| AUC† (hr-mIU/mL) | 726.2 (243.0) | 656.1 (233.7) | 622.7 (153.0) | 546.2 (91.2) |

†Single dose $C_{max}$, $AUC_{120}$ and multiple dose $C_{maxss}$, $AUC_{ss}$

### Absorption
The SC route of administration trends toward greater bioavailability than the IM route for single and multiple doses of Menopur®.

### Distribution
Human tissue or organ distribution of FSH and LH has not been studied for Menopur®.

### Metabolism
Metabolism of FSH and LH has not been studied for Menopur® in humans.

### Elimination
The elimination half-lives for FSH in the multiple-dose phase were similar (11-13 hours) for Menopur® SC and Menopur® IM.

### Pediatric Populations
Menopur® has not been studied in the pediatric population.

### Geriatric Populations
Menopur® has not been studied in the geriatric population.

### Special Populations
The safety and efficacy of Menopur® in renal and hepatic insufficiency have not been studied.

### Drug Interactions
No drug/drug interaction studies have been conducted for Menopur® in humans.

## CLINICAL STUDIES
The efficacy and safety of Menopur® have been established in one randomized, controlled clinical study, 0399E, of women undergoing *in vitro* fertilization (IVF) or IVF plus intracytoplasmic injection to achieve pregnancy.

Study 0399E was a Phase 3, randomized, open-label, multicenter, multinational (in Europe and Israel), comparative clinical trial of ovulatory, infertile females undergoing ovarian stimulation to produce multiple follicles for IVF and embryo transfer (IVF/ET) after pituitary suppression with a GnRH agonist. A total of 373 patients were randomized to the Menopur® arm. Randomization was stratified by insemination technique [conventional in-vitro fertilization (IVF) vs. intra-cytoplasmic sperm injection (ICSI)]. Efficacy was assessed based on the primary efficacy parameter of continuing pregnancy. The initial daily dose of Menopur® was 225 IU SC for five days. Thereafter, the dose was individualized according to each patient's response, up to a maximum of 450 IU/day for a total maximum duration of stimulation of 20 days. Treatment outcomes are summarized in Table 2.

**Table 2: Efficacy Outcomes for IVF Study 0399E (one cycle of treatment)**

| Parameter | Menopur® SC |
|---|---|
| | n=373 |
| Continuing Pregnancy (%)[a] | 87 (23)[b] |
| Clinical Pregnancy (%) | 98 (26)[c] |

[a]Continuing pregnancy was defined as ultrasound visualization of a gestational sac with fetal heartbeat at ≥10 weeks after ET

[b]Non-inferior to comparator recombinant human FSH based on a two-sided 95% confidence interval, intent-to-treat analysis

[c]Secondary efficacy parameter. Study 0399E was not powered to demonstrate differences in this parameter

## INDICATIONS AND USAGE
Menopur® administered subcutaneously is indicated for the development of multiple follicles and pregnancy in the ovulatory patients participating in an ART program.

### Selection of Patients
1. A thorough gynecologic and endocrinologic evaluation, including an assessment of pelvic anatomy must be performed before treatment with Menopur®. Patients with tubal obstruction should receive Menopur® only if enrolled in an IVF program.
2. Primary ovarian failure should be excluded by the determination of gonadotropin levels.
3. Careful examination should be made to rule out the presence of an early pregnancy.
4. Patients in late reproductive life have a greater predilection to endometrial carcinoma as well as a higher incidence of anovulatory disorders. A thorough diagnostic evaluation should always be performed in patients who demonstrate abnormal uterine bleeding or other signs of endometrial abnormalities before starting Menopur® therapy.
5. Evaluation of the partner's fertility potential should be included in the workup.

## CONTRAINDICATIONS
Menopur® is contraindicated in women who have:
1. A high FSH level indicating primary ovarian failure.
2. Uncontrolled thyroid and adrenal dysfunction.
3. An organic intracranial lesion such as a pituitary tumor.
4. Sex hormone dependent tumors of the reproductive tract and accessory organs.
5. Abnormal uterine bleeding of undetermined origin.
6. Ovarian cysts or enlargement not due to polycystic ovary syndrome.
7. Prior hypersensitivity to menotropins or Menopur®.
8. Menopur® is not indicated in women who are pregnant. There are limited human data on the effects of menotropins when administered during pregnancy.

## WARNINGS
Menopur® is a drug that should only be used by physicians who are thoroughly familiar with infertility problems. It is a potent gonadotropic substance capable of Ovarian Hyperstimulation Syndrome (OHSS) in women with or without pulmonary or vascular complications. Gonadotropin therapy requires a certain time commitment by physicians and supportive health professionals, and its use requires the availability of appropriate monitoring facilities (see **PRECAUTIONS – Laboratory Tests**).

### Overstimulation of the Ovary During Menopur® Therapy
Ovarian Enlargement: Mild to moderate uncomplicated ovarian enlargement which may be accompanied by abdominal distension and/or abdominal pain occurs in approximately 5 to 10% of women treated with menotropins and hCG, and generally regresses without treatment within two or three weeks. The lowest dose consistent with expectation of good results and careful monitoring of ovarian response can further minimize the risk of overstimulation.

If the ovaries are abnormally enlarged on the last day of Menopur® therapy, hCG should not be administered in this course of treatment; this will reduce the chances of development of the Ovarian Hyperstimulation Syndrome (OHSS).

OHSS: OHSS is a medical event distinct from uncomplicated ovarian enlargement. OHSS may progress rapidly to become a serious medical event. It is characterized by an apparent dramatic increase in vascular permeability which can result in a rapid accumulation of fluid in the peritoneal cavity, thorax, and potentially, the pericardium. The early warning signs of development of OHSS are severe pelvic pain, nausea, vomiting, and weight gain. The following symptomatology has been seen with cases of OHSS: abdominal pain, abdominal distension, gastrointestinal symptoms including nausea, vomiting and diarrhea, severe ovarian enlargement, weight gain, dyspnea, and oliguria. Clinical evaluation may reveal hypovolemia, hemoconcentration, electrolyte imbalances, ascites, hemoperitoneum, pleural effusions, hydrothorax, acute pulmonary distress, and thromboembolic events (see **Pulmonary and Vascular Complications**). Transient liver function test abnormalities suggestive of hepatic dysfunction, which may be accompanied by morphologic changes on liver biopsy, have been reported in association with the OHSS.

In the IVF clinical study, 0399E, OHSS occurred in 7.2% of the 373 Menopur® treated women.

Cases of OHSS are more common, more severe and more protracted if pregnancy occurs. OHSS develops rapidly; therefore patients should be followed for at least two weeks after hCG administration. Most often, OHSS occurs after treatment has been discontinued and reaches its maximum at about seven to ten days following treatment. Usually, OHSS resolves spontaneously with the onset of menses. If there is evidence that OHSS may be developing prior to hCG administration (see **PRECAUTIONS – Laboratory Tests**), the hCG should be withheld. If severe OHSS occurs, treatment must be stopped and the patient should be hospitalized.

A physician experienced in the management of the syndrome, or who is experienced in the management of fluid and electrolyte imbalances, should be consulted.

### Pulmonary and Vascular Complications
Serious pulmonary conditions (eg, atelectasis, acute respiratory distress syndrome) have been reported. In addition, thromboembolic events both in association with, and separate from, the OHSS have been reported following menotropins therapy. Intravascular thrombosis and embolism, which may originate in venous or arterial vessels, can result in reduced blood flow to critical organs or the extremities. Sequelae of such events have included venous thrombophlebitis, pulmonary embolism, pulmonary infarction, cerebral vascular occlusion (stroke), and arterial occlusion resulting in loss of limb. In rare cases, pulmonary complications and/or thromboembolic events have resulted in death.

### Multiple Pregnancies
In the clinical trial multiple pregnancy as diagnosed by ultrasound occurred in 35.3% (n=30) of 85 total pregnancies.

The patient and her partner should be advised of the potential risk of multiple births before starting treatment.

PERF LINE

PERF LINE

**PATIENT INFORMATION**
# MENOPUR® 75 IU
(menotropins for injection, USP)

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 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 nonprescription 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 side effects 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®**

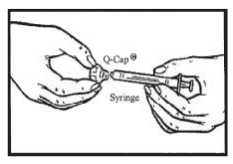
**Make sure your doctor and/or nurse has taught you about mixing and injecting Menopur® before you do it yourself. Your doctor will decide on the dose that is best for you. This dose may be increased or decreased as your treatment goes on. Do not change the dose of Menopur® until your doctor tells you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

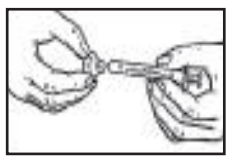
**1. Before you start**
- Wash your hands well with soap. Use a soap that kills bacteria. Dry your hands with a clean towel.
- Use alcohol to clean the surface you will be working on. Lay out all the things you will need.
- Have these supplies ready as you start to prepare Menopur®:
  - The vial(s) of Menopur® powder and 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.

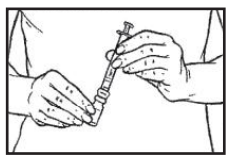
**2. Preparing your Menopur® and filling the syringe**
- Remove the syringe from the wrapper. If there is a capped needle on the syringe, remove the needle by twisting it counterclockwise (to the left). Open one Q•Cap by peeling back the label and set the blister pouch with the Q•Cap aside. Do not take 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.



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



**PRECAUTIONS**

**General**

Careful attention should be given to the diagnosis of infertility in the selection of candidates for Menopur® therapy (see **INDICATIONS AND USAGE – Selection of Patients**).

**Information for Patients**

Prior to therapy with Menopur®, patients should be informed of the duration of treatment and the monitoring of their condition that will be required. Possible adverse reactions (see **ADVERSE REACTIONS** section) and the risk of multiple births should also be discussed.

**Laboratory Tests**

The combination of both estradiol levels and ultrasonography are useful for monitoring the growth and development of follicles, timing hCG administration, as well as minimizing the risk of the OHSS and multiple gestations.

The clinical confirmation of ovulation, is determined by:

a) A rise in basal body temperature;
b) Increase in serum progesterone; and
c) Menstruation following the shift in basal body temperature.

When used in conjunction with indices of progesterone production, sonographic visualization of the ovaries will assist in determining if ovulation has occurred. Sonographic evidence of ovulation may include the following:

a) Fluid in the cul-de-sac;
b) Ovarian stigmata; and
c) Collapsed follicle.

Because of the subjectivity of the various tests for the determination of follicular maturation and ovulation, it cannot be overemphasized that the physician should choose tests with which he/she is thoroughly familiar.

**Carcinogenesis and Mutagenesis**

Long-term toxicity studies in animals have not been performed to evaluate the carcinogenic potential of menotropins.

**Pregnancy**

*Pregnancy Category X:* See **CONTRAINDICATIONS** section.

**Nursing Mothers**

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised if menotropins are administered to a nursing woman.

**Pediatric Patients**

Safety and effectiveness in pediatric patients have not been established.

**Geriatric Patients**

Safety and effectiveness in geriatric patients have not been established.

**ADVERSE REACTIONS**

The safety of Menopur® was examined in 3 clinical studies that enrolled a total of 575 patients receiving Menopur® in the IVF and OI studies. All adverse events (without regard to causality assessment) occurring at an incidence of ≥2% in women treated with Menopur® are listed in Table 3.

**Table 3: Highly Purified Menotropin SC and IM in Female Patients Undergoing IVF and OI Adverse Events with Onset on or After GnRH Administration, COSTART Classification (for Incidence of 2% or Greater)**

| Body System/Preferred Term | | IVF* n=499 | | OI** n=76 | |
|---|---|---|---|---|---|
| | | N | % | N | % |
| Body as a whole | Abdomen enlarged | 12 | 2.4 | 0 | 0.0 |
| | Abdominal cramps | 30 | 6.0 | 5 | 6.6 |
| | Abdominal fullness | 16 | 3.2 | 7 | 9.2 |
| | Abdominal pain | 88 | 17.6 | 7 | 9.2 |
| | Back pain | 16 | 3.2 | 0 | 0.0 |
| | Elevated estradiol | 12 | 2.4 | 0 | 0.0 |
| | Flu syndrome | 13 | 2.6 | 1 | 1.3 |
| | Flushing | 12 | 2.4 | 0 | 0.0 |
| | Headache | 170 | 34.1 | 12 | 15.8 |
| | Injection site pain | 27 | 5.4 | 0 | 0.0 |
| | Injection site reaction | 48 | 9.6 | 9 | 11.8 |
| | Malaise | 14 | 2.8 | 2 | 2.6 |
| | Pain | 16 | 3.2 | 2 | 2.6 |
| Cardiovascular | Migraine | 12 | 2.4 | 0 | 0.0 |
| Digestive | Constipation | 8 | 1.6 | 0 | 0.0 |
| | Diarrhea | 14 | 2.8 | 2 | 2.6 |
| | Nausea | 60 | 12.0 | 6 | 7.9 |
| | Vomiting | 21 | 4.2 | 2 | 2.6 |
| Nervous | Dizziness | 13 | 2.6 | 0 | 0.0 |
| Respiratory | Cough increased | 8 | 1.6 | 2 | 2.6 |
| | Respiratory disorder | 29 | 5.8 | 3 | 3.9 |
| Urogenital | Breast tenderness | 9 | 1.8 | 2 | 2.6 |
| | Hot flash | 3 | 0.6 | 2 | 2.6 |
| | Menstrual disorder | 16 | 3.2 | 0 | 0.0 |
| | OHSS | 19 | 3.8 | 10 | 13.2 |
| | Pelvic cramps | 0 | 0.0 | 3 | 3.9 |
| | Pelvic discomfort | 2 | 0.4 | 2 | 2.6 |
| | Post retrieval pain | 32 | 6.4 | 0 | 0.0 |
| | Uterine spasm | 8 | 1.6 | 3 | 3.9 |

* INCLUDES IM AND SC SUBJECTS FROM PROTOCOLS MFK/IVF/0399E AND MENOPUR 2000-02.
**INCLUDES IM AND SC SUBJECTS FROM PROTOCOL MENOPUR 2000-01.

**DRUG ABUSE AND DEPENDENCE**

There have been no reports of abuse or dependence with menotropins.

**OVERDOSAGE**

Aside from possible ovarian hyperstimulation (see **WARNINGS**), little is known concerning the consequences of acute overdosage with Menopur®.

**DOSAGE AND ADMINISTRATION**

**1. Dosage:**

**Assisted Reproductive Technologies**

The recommended initial dose of Menopur® for patients who have received a GnRH agonist for pituitary suppression is 225 IU. Based on clinical monitoring (including serum estradiol levels and vaginal ultrasound results) subsequent dosing should be adjusted according to individual patient response. Adjustments in dose should not be made more frequently than once every two days and should not exceed 150 IU per adjustment. The maximum daily dose of Menopur® given should not exceed 450 IU and dosing beyond 20 days is not recommended.

Once adequate follicular development is evident, hCG should be administered to induce final follicular maturation in preparation for oocyte retrieval. The administration of hCG must be withheld in cases where the ovaries are abnormally enlarged on the last day of therapy. This should reduce the chance of developing OHSS.

**2. Administration:**

Dissolve the contents of one to six vials of Menopur® in one mL of sterile saline and **ADMINISTER SUBCUTANEOUSLY** immediately. Any unused reconstituted material should be discarded.

Parenteral drug products should be visually inspected for particulate matter and discoloration prior to administration, whenever solution and container permit.

**The lower abdomen (alternating sides) should be used for subcutaneous administration.**

**HOW SUPPLIED**

Menopur® (menotropins for injection, USP) is supplied in sterile vials as a lyophilized, white to off-white powder or pellet.

Each vial of Menopur® is accompanied by a vial of sterile diluent containing 2 mL of 0.9% Sodium Chloride Injection, USP:

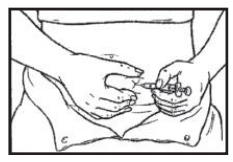
75 IU FSH and 75 IU of LH activity, supplied as:
NDC 55566-7501-1: Box of 5 vials + 5 vials diluent.
NDC 55566-7501-2: Box of 5 vials + 5 vials diluent + 5 Q•Cap® vial adapters.

**STORAGE**

Lyophilized powder may be stored refrigerated or at room temperature (3° to 25°C/37° to 77°F). Protect from light. Use immediately after reconstitution. Discard unused material.

**DIRECTIONS FOR USING Menopur®**

1. Wash hands thoroughly with soap and water.
2. Before injections, the septum tops of the vials should be wiped with an aseptic solution to prevent contamination of the contents.
3. To prepare the Menopur® solution, inject 1 mL of Sterile Saline for Injection, USP into the vial of Menopur®. **DO NOT SHAKE**, but gently swirl until the solution is clear. Generally, the Menopur® dissolves immediately. Check the liquid in the container. If it is not clear or has particles in it, **DO NOT USE IT**.
4. For patients requiring a single injection from multiple vials of Menopur®, up to 6 vials can be reconstituted with 1 mL of Sterile Saline for Injection, USP. This can be accomplished by reconstituting a single vial as described above (see step 3). Then draw the entire contents of the first vial into a syringe, and inject the contents into a second vial of lyophilized Menopur®. Gently swirl the second vial, as described above, once again checking to make sure the solution is clear and free of particles. This step can be repeated with 4 additional vials for a total of up to 6 vials of lyophilized Menopur® into 1 mL of diluent.
5. Draw the reconstituted Menopur® into an empty, sterile syringe.
6. Hold the syringe pointing upwards and gently tap the side to force any air bubbles to the top; then squeeze the plunger gently until all the air has been expelled and only Menopur® solution is left in the syringe.
7. Menopur® works if it is injected **SC**. The recommended sites for SC injection are either side of the lower abdomen alternating between left and right sides of the lower abdomen below the naval. SC injection of Menopur® into the thigh is not recommended unless the lower abdomen is not usable because of scarring, surgical deformity or other medical conditions.
8. The injection site should be swabbed with alcohol. Clean about two inches around the point where the needle will go in and let the alcohol dry for at least one minute before proceeding.
9. For **SC** injection, the needle should be inserted at a 90° angle to the skin surface.



10. If the needle is correctly positioned, it will be difficult to draw back on the plunger. Any blood drawn into the syringe means the needle tip has penetrated a vein or artery. If this happens, the needle should be withdrawn, cover the injection site with a swab containing alcohol and apply pressure; the site should stop bleeding in a minute or two. After withdrawing the needle, replace with a sterile needle and administer the injection.
11. Once the needle is properly placed, depress the plunger **slowly** and steadily, so the solution is correctly injected and the skin or muscle tissue is not damaged.
12. Withdraw the needle quickly and apply pressure to the site with a swab. If bleeding does not stop within a few minutes, place a clean piece of gauze and/or adhesive bandage over the site.
13. Use the disposable syringe only once and dispose of it properly. Discard the used needle and syringe into your safety container. Do not reuse your injection materials.

Toll free number for providers and patients to call with questions:
1-(888)-FERRING (1-(888)-337-7464)

**Rx only**

Vials of sterile diluent of 0.9% Sodium Chloride Injection, USP manufactured for Ferring Pharmaceuticals Inc.

**MANUFACTURED FOR:**

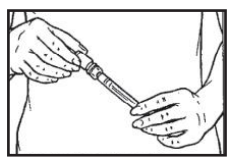
FERRING PHARMACEUTICALS

FERRING PHARMACEUTICALS INC.
Parsippany, NJ 07054

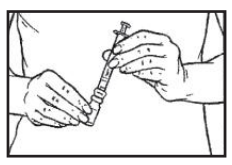
6314-02
Rev 07/2012

PERF LINE

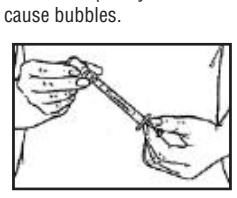
- Push the syringe plunger down to transfer the air from the syringe into the vial. Keeping the syringe and Q•Cap together, turn the vial upside down and pull back on the syringe plunger to withdraw from the vial the amount of sterile diluent specified by your doctor.



- 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.



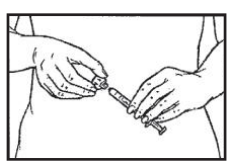
- Slowly inject the sterile diluent into the vial containing Menopur® powder. Gently swirl until the Menopur® powder is completely dissolved. Do not shake the vial as this will cause bubbles.
- As soon as the powder has completely dissolved, turn the vial upside down and withdraw all of the Menopur®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



Note to patients who need multiple vials: Some patients need to take more than 1 vial of Menopur®. If your doctor tells you to do this, prepare the first vial of Menopur® with sterile diluent. 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**

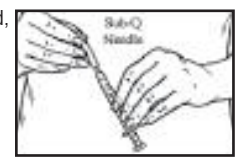
- When you have finished reconstituting the last vial necessary for your injection and have withdrawn all the medicine into the syringe, twist the syringe counterclockwise while holding the Q•Cap steady to remove the syringe from the Q•Cap. Discard the Q•Cap with the attached medicine vial.



- 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.**

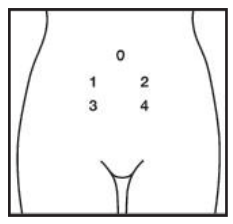
- While holding the syringe pointing upward, twist the needle clockwise (to the right) onto the syringe.



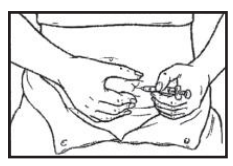

- Hold the syringe straight up. Draw back slightly on the plunger and tap the syringe so that any air bubbles rise to the top. Slowly press the plunger until all the air is out of the syringe and a small drop of solution forms at the tip of the needle.
- Tap the syringe to remove the drop of solution 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 diluent.
- **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**.

**MANUFACTURED FOR:**

FERRING PHARMACEUTICALS

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