

Dispensing this medicine requires a doctor's prescription

MENOPUR® 75IU

Powder and solvent for reconstituting a solution for subcutaneous or intra-muscular injection

Active ingredient name and quantity - each vial of powder contains menotrophin (hMG): LH 75IU, FSH 75 IU

Inactive ingredients and allergens: See Section 6 'Further Information'. See also 'Important information about some of this medicine's ingredients' in Section 2.

Read the entire leaflet carefully before using this medicine.

This leaflet contains concise information about this medicine. If you have further questions, refer to your doctor or pharmacist.

This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar to yours.

This medicine is not intended for children and the elderly.

If any side effect gets worse, or if you notice any side effect not mentioned in this leaflet, please tell your doctor or pharmacist.

What is Menopur and what is it used for?

Menopur contains a medicine called menotrophin. It is a mixture of hormones extracted from the urine of women who have passed menopause.

Dosage of these hormones is given in international units (IU).

Menopur helps reproductive organs to work normally in both women and men. A fertility specialist should supervise your treatment with this medicine.

1. What is this medicine intended for?

In women: Infertility due to ovarian insufficiency, stimulating follicle/s growth in fertility treatments.

In men: Sterility due to testicular insufficiency, stimulating spermatogenesis in combined treatment with the hormone human chorionic gonadotropin (hCG).

Therapeutic group: gonadotropins.

2. Before using Menopur

❑ Do not use this medicine if:

Men and Women:

- You are hypersensitive (allergic) to menotrophin or any of this medicine's other ingredients listed in Section 6.
- You have hyperprolactinemia (high levels of the hormone prolactin), you have tumors in your pituitary or hypothalamus (a part of your brain that regulates conditions in your body including your body temperature and blood pressure).

In women:

- When you are pregnant or breastfeeding.
- You have ovarian cysts or enlarged ovaries that are not due to polycystic ovary syndrome (a syndrome that prevents eggs from being released from the ovaries).
- You have vaginal bleeding for an unknown reason.
- You have a malignant tumor in your womb, ovaries or breasts.
- You have primary ovarian failure (your ovaries are not working properly).
- You have blocked fallopian tubes, unless you are given this treatment as part of IVF treatment or ICSI (injection of sperm into the cell's internal fluid) treatment.
- You are experiencing symptoms of premature menopause.
- You have physical problems in your reproductive organs (womb, fallopian tubes, ovaries, or cervix).
- Your womb has been removed (you have had a hysterectomy).
- You have benign fibroid tumors (tumors in your womb that are not cancer).

Men:

You have cancer of the prostate and/or testicles.

Special warnings about using this medicine

Consult your doctor before starting treatment with if:

- You have had infertility treatment in the past.
- You have, or someone in your family has, a history of blood clots. Treatment with Menopur may cause an increased risk of blood clots. Pregnancy also increases the risk of blood clots.

If you are taking or have recently taken other medicines, including non-prescription medication and nutritional supplements, tell your doctor or pharmacist.

Tests and follow-up

Before you start treatment, your doctor will order to perform the following tests:

Men and women: Test for thyroid and adrenal gland function. Test to ensure there are no tumors in the pituitary or in the hypothalamus.

Women: Test for ovary function, test to measure blood levels of the hormone prolactin.

Pregnancy and breastfeeding

Do not use this medicine if you are pregnant or breastfeeding.

Important information about some of this medicine's ingredients

This medicine contains lactose. Tell your doctor if you are sensitive to this ingredient.

3. How to use this medicine?

Always use according to the doctor's instructions.

Check with your doctor or pharmacist if you are not sure.

Only your doctor will determine your dose and how you should take the medicine.

This medicine is not intended for children and the elderly. Do not swallow this medicine! Do not exceed the recommended dose.

The recommended dose depends on the reason you have been given this treatment; your doctor will monitor your response to the treatment and this will help the doctor to work out what dose you need and how long you need to use it.

In women:

For infertility (to help follicles mature):

If you are having periods, your treatment will start within the first 7 days of your menstrual cycle.

Menopur can be given every day for 3 weeks or every other day for 6 days (three doses in total).

In IVF treatment:

The standard dose is 75 IU or 300 IU a day.

In men:

For low sperm count:

The standard dose is 75 IU or 150 IU twice or three times a week. Treatment usually continues for three to four months at least.

Instructions for use

For subcutaneous or intramuscular injection

If your doctor has told you to inject Menopur yourself, follow your doctor's instructions.

Your first Menopur 75 IU injection must be given under the supervision of a doctor.

Dissolving Menopur:

Menopur 75 IU is provided in powder form and must be dissolved before it can be used. The solvent which you should use to dissolve the powder is provided in the kit.



How to inject:



- Insert the needle into the ampule that contains the solvent.
- Draw the solvent from the ampule into the syringe.
- Insert the needle through the rubber cap of the powder vial and slowly inject all the solvent. Aim at the sides of the vial, to avoid creating bubbles.
- Wait for the powder to dissolve completely.

- Do not shake! You may swirl the vial to help the powder dissolve.
- Do not use the solution if it is not clear or if it contains particles.

- Draw the solution back into the syringe.

- Change the long needle that is attached to the syringe to the short thin needle that will be used for injecting.
- Hold the syringe with the needle pointing up and gently tap the syringe until the air bubbles collect at its tip. Gently push the plunger up until the air bubbles are out and a drop of solution appears on the tip of the needle.

- Choose an injection site as instructed by your doctor or nurse.
- Disinfect the injection site. To inject, pinch your skin to make a fold, and insert the needle in one swift motion at a 90 degree angle to your body.
- Press the plunger down to inject the solution, and then take the needle out of your skin. After taking the needle out, apply pressure to the injection site to stop any bleeding. Gently massage the injection site to disperse the solution under the skin.

If you have accidentally taken an overdose, or if a child has accidentally swallowed some medicine, go immediately to a doctor or a hospital emergency room and bring the medicine package with you.

If you forget to take the medicine at the scheduled time, do not take a double dose. Persist with the treatment as recommended by your doctor.

Do not take medicines in the dark! Check the label and dose each time you take the medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

In addition to the medicine's desired effect, some users may experience side effects when using it.

Do not be alarmed by this list of side effects. You may not experience any of them.

In women:

Using this medicine can cause overstimulation of your ovaries. As a result, you may develop ovarian cysts which can rupture and cause bleeding inside your abdomen. Overstimulation of your ovaries can also cause edema, producing less urine, reduced blood pressure, and blood clots. This is a common side effect (occurs in 1-10 out of 100 users).

At the first signs of ovarian hyper-stimulation, for example pain and swelling of the abdomen, nausea, vomiting, diarrhea, weight gain, difficulty breathing, thirst, producing less urine, immediately discontinue treatment and see a doctor!

With pregnancy, ovary hyper-stimulation may be intensive, continue over a long period of time, and be more dangerous.

Using this medicine may cause increased frequency of pregnancies with more than one baby.

If Menopur treatment has resulted in a pregnancy, there is a greater chance of the following side effects happening compared with a naturally achieved pregnancy: being pregnant with more than one baby, ectopic pregnancy, miscarriage, slightly higher risk of your baby being born with defects.

In men and women: Stop using and see a doctor or go to hospital immediately, if you experience an allergic reaction with the following side effects: itching, rash, swelling of your face, lips, or throat, difficulty breathing, wheezing, chest pressure or cough.

Common side effects – affect 1-10 in 100 users: headache, pain or inflammation at the injection site.

Uncommon side effects – affect 1-10 in 1,000 users: Blood clots in the veins, usually in the legs (DVT - deep vein thrombosis).

Rare side effects - affect 1-10 in 10,000 users: hypersensitivity and fever.

Very rare side effects - affect less than one user out of 10,000: When used in the long-term, your body may produce antibodies that could make the treatment ineffective.

In men only: Using this medicine together with hCG can occasionally lead to enlargement of breasts (gynecomastia).

If any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Attention! Avoid contact with the eyes.

Reporting side effects

You can report side effects to the Ministry of Health (MoH) by following the link 'Reporting Side Effects of Medication' on the MoH home page (www.health.gov.il) which links to an online form for reporting side effects or by clicking the link:

<https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>

5. How to store this medicine?

Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place out of reach of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.

Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.

Store below 25°C.

Use immediately after reconstitution.

Do not discard the medicine via wastewater or household waste. Ask the pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

6. Additional information

In addition to the active ingredients this medicine also contains:

Powder: lactose monohydrate, polysorbate 20, sodium hydroxide, hydrochloric acid

Solvent: sodium chloride, dilute hydrochloride acid, water for injection

What does the medicine look like and what are the contents of the package:

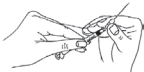
Each package contains: 5 powder vials and 5 solvent ampules, or 10 powder vials and 10 solvent ampules. Not all package sizes may be marketed.

Registration holder's name and address: Ferring Pharmaceuticals Ltd., Hashita 8 St., Industrial Park, Caesarea 3088900.

Manufacturer name and address: Ferring, Germany.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 123 86 30045

This leaflet was reviewed and approved by the Ministry of Health in: September 2017.



- Attach the long, thick needle to the syringe.



- Hold the ampule with the red dot pointing toward you and break the ampule.