

This medicine is dispensed with a doctor's prescription only

Menopur 75 IU

Powder and solvent for reconstituting a solution for subcutaneous or intramuscular injection

Composition: Each vial with powder contains menotropin (hMG): LH 75 IU, FSH 75 IU.

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

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about the medicine. If you have any further questions, consult 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.

1. What is this medicine intended for?

In women: Infertility that is caused by ovary failure, promoting follicle growth in fertility treatments.

In men: Infertility that is caused by testicular failure, promoting semen production in combination with human chorionic gonadotropin (hCG) hormone treatment.

Therapeutic group: Gonadotropins.

2. Before using MENOPUR

Do not use this medicine if:

In women:

- you are pregnant or breastfeeding
- you have vaginal bleeding for an unknown reason
- you have tumors of the womb (uterus), ovaries or breasts
- you have cysts in your ovaries or are diagnosed with enlarged ovaries that are not due to polycystic ovarian disease (a condition that prevents eggs from being released from the ovaries)
- you are having early menopause
- you have certain physical problems in your reproductive organs (womb, fallopian tubes, ovaries or cervix)
- your womb has been removed (hysterectomy)
- you have fibroids (tumors in your womb that are not cancer)

In men:

- you have cancer of your prostate gland or of the testicles

Special warnings about using this medicine:

Before starting treatment, you and your partner should be evaluated by a doctor for the causes of your fertility problems. Special attention should be given to diagnosis and treatment of the following conditions:

- underactive thyroid or adrenal glands
- high levels of a hormone called prolactin (hyperprolactinemia)
- tumors of the pituitary gland (a gland located on the base of the brain which produces certain hormones, including growth hormone)
- tumors of the hypothalamus (an area located under the part of the brain called the thalamus which controls the conditions within your body including body temperature and blood pressure)

During the course of treatment with this medicine:

Consult your doctor immediately if you experience:

- pain or swelling of the stomach
- nausea or vomiting
- weight gain
- difficulty in breathing
- decreased urination

Tell your doctor straight away, even if the symptoms described above develop some days after you are given the last injection.

These can be signs of excessive activity in the ovaries and it might get worse.

If these symptoms become severe, the fertility treatment must be stopped and you should receive treatment in hospital.

Keeping to your prescribed dose and careful monitoring of your treatment will reduce your chances of getting these symptoms.

If you stop taking MENOPUR some of these symptoms may persist. Please contact your doctor immediately if you experience any of these symptoms.

While you are being treated with this medicine, your doctor will normally arrange for you to have ultrasound scans and sometimes blood tests to monitor your response to treatment.

Being treated with hormones like MENOPUR can increase the risk of:

ectopic pregnancy (pregnancy outside of the womb), if you have a history of fallopian tube disease
miscarriage
multiple pregnancy (twins, triplets, etc.)
congenital malformations (physical defects present in baby at birth)

Some women were given fertility treatment with multiple medicines have developed tumors in the ovaries and other reproductive organs. It is not known if treatment with hormones like MENOPUR causes these problems.

Blood clot formation inside blood vessels (veins or arteries) are more likely to occur in women who are pregnant. Fertility treatment can increase the chances of this happening, especially if you are overweight or are known to have a blood clotting disease (thrombophilia) or if you or someone in your family (blood relative) has had blood clots. Tell your doctor if you think this applies to you.

Children: This medicine is not used in children.

Other medicines and MENOPUR

If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist.

Clomiphene citrate is another medicine used in the treatment of infertility. If MENOPUR is used at the same time as clomiphene citrate the effect on the ovaries may be increased.

Pregnancy and breastfeeding

Do not use MENOPUR during pregnancy or breastfeeding.

Driving and using machines

MENOPUR is unlikely to affect your ability to drive and use machines.

Important information about some of this medicine's ingredients

MENOPUR contains less than 1 mmol sodium (23 mg) per dose, so it is essentially 'sodium-free'.

The medicine also contains lactose (which is a type of sugar). If you have been told by your doctor that you cannot tolerate or digest certain sugars, talk to your doctor before starting treatment with this medicine.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine. Only your doctor will determine your dose and how you should take this medicine.

This medicine is not intended for children or the elderly.

Do not Swallow this medicine!

Do not exceed the recommended dose.

The recommended dose depends on the reason you are being treated. Your doctor will monitor how you respond to treatment. This will help your doctor to work out what dose you need and how long you need to use MENOPUR.

In women:

Infertility (to help with follicle maturation):

If you menstruate, treatment should start during the first 7 days of your menstrual cycle.

You can either be given MENOPUR every day for 3 weeks or every other day for 6 days (a total of three doses).

Women in IVF program:

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

In men:

For low sperm count:

The usual dose is 75 or 150 IU two or three times a week. Treatment is normally continued for at least 3 or 4 months.

Directions for use

For injection under the skin or into a muscle

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

Your first injection of MENOPUR 75 IU must be given with a doctor's supervision. Your doctor will monitor your reaction to treatment. If an excessive response occurs, your doctor may decide to stop treatment with MENOPUR and not give you the hCG injection. In this case, you will have to use a barrier method of contraception (such as a condom) or not have sexual intercourse until your next period has started. For the following treatment cycle your doctor will give you a lower dose of MENOPUR than before.

Dissolving MENOPUR:

MENOPUR 75 IU is provided as a powder and must be dissolved before it is injected. The solvent which you will use to dissolve MENOPUR is provided in the kit.

The powder should only be dissolved immediately before use.

Please note: One drop of solvent can dissolve all the powder immediately, leading to the impression that no powder was present in the vial. Check the vial for powder before adding the solvent.

What to do:



- Attach the long, thick needle (reconstitution needle) to the syringe.



- Break the ampule keeping the red dot toward you.



- Insert the needle into the ampule with solvent.
- Draw up the solvent from the ampule into the syringe.
- Insert the needle through the rubber stopper of the powder vial and slowly inject all of the solvent.
- Aim at the side of the vial to avoid creating bubbles.
- The powder should quickly dissolve (within 2 minutes) to form a clear solution.



To help the powder dissolve, swirl the solution. **Do not shake as this will cause air bubble to form! Do not use the solution if it is not clear or if it contains particles.**



- Draw up the solution back into the syringe.

If you have been prescribed more than one vial per injection, you can draw up the solution (the first MENOPUR dilution) back into the syringe and inject it into the second vial. You can dissolve this way up to three vials of powder in total - but only if your doctor has told you to do so.

How to inject:



- Once you have your prescribed dose drawn up into the syringe, change the long needle that you attached to the syringe to a short, thin needle (the injection needle)
- Hold the syringe with the needle pointing upward and flick it gently so the air bubbles will collect at the top. Push the plunger in gently until a drop of solution appears at the tip of the needle.

- Choose an injection site according to instructions from your doctor or nurse (for example the front of the thigh, abdomen, etc.)
- Disinfect the injection site.

- To inject, pinch the skin to produce a fold and insert the needle in one swift motion at 90 degrees to the body.

Press down on the plunger to inject the solution and then pull the needle out of the skin.

- After removing the needle, apply pressure to the injection site to stop any bleeding. Gently massaging the injection site will help to disperse the solution under the skin.

- Do not put used syringes into domestic waste. Ask your pharmacist how to dispose of them.

If you have taken an overdose, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to 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. Adhere to the treatment as recommended by your doctor.

Do not take medicines in the dark! Check the label and dose every time you take 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

Like with all medicines, using MENOPUR may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

In women:

If you notice any of the following signs, consult your doctor immediately. They may be signs of ovarian hyperstimulation syndrome (OHSS), especially in women with polycystic ovaries, and you may need urgent medical treatment.

Symptoms include: nausea; vomiting; diarrhea; weight gain; pain or swelling of the abdomen.

In cases of severe OHSS:

fluid build-up in the abdomen, pelvis, and/or chest; difficulty in breathing; decreased urination (producing small amounts of urine when you go to the toilet or going to the toilet less often); formation of blood clots (thromboembolism); twisted ovary (ovarian torsion).

If you notice any of the above signs, consult your doctor immediately!

Side effects that can happen in both women and men: Stop treatment if you experience an allergic reaction that includes the following side effects: itching, skin rashes, swelling of the face, lips or throat and difficulty in breathing. In these cases, consult your doctor or go to hospital immediately.

Common side effects (affect 1-10 in 100 users):

pain or swelling of the abdomen; headache; nausea; pelvic pain; overstimulation of the ovaries resulting into high levels of activity (OHSS) pain or inflammation at the injection site (redness, bruising, swelling and/or itching).

Uncommon side effects (affect up to 1 in 100 users):

vomiting;discomfort in stomach; diarrhea; fatigue; lightheadedness; sacs of fluid in the ovaries (ovarian cysts); breast pain, breast discomfort, breast tenderness, nipple pain and breast swelling; hot flashes.

Rare side effects (affect 1-10 in 10,000 users):

acne; skin rash.

Side effects of unknown frequency:

eyesight disturbances; allergic reactions; pain in muscles and joints (for example back pain, neck pain and pain in arms and legs); twisted ovary (ovarian torsion) as a complication of OHSS; itching; hives.

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

Reporting side effects

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: <https://sideeffects.health.gov.il>

5. How to store the medicine?

Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight 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) which is stated on the package. The expiry date refers to the last day of that month.

Storage conditions

Store below 25°C.

Use immediately after reconstituting. Do not dispose of medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. 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, diluted hydrochloric acid, water for injection.

What the medicine looks like and contents of the pack:

Product packs contain: 5 vials with powder and 5 vials with solvent, or 10 vials with powder and 10 vials with solvent.

Not all pack sizes may be marketed.

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

Manufacturer's name and address: Ferring, Germany.

Revised in May 2020.

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