

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

Menopur Multidose 600 IU and 1200 IU

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

Composition:

Menopur Multidose 600 IU

Each vial with powder contains menotropin (hMG):
LH 600 IU and FSH 600 IU

Menopur Multidose 1200 IU

Each vial with powder contains menotropin (hMG):
LH 1200 IU and FSH 1200 IU

Inactive ingredients: 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 hCG 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 and/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 abdomen
- 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 using MENOPUR you might still experience these symptoms. Please contact your doctor immediately if any of these symptoms occur.

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)

Women who 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 MENOPUR?

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.

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.

How to inject yourself:

You must be trained by the clinic staff to make the injection before you use this product.

Your first self-injection will be performed under medical 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.

Directions for use:

For injection under the skin or into a muscle

Dissolving MENOPUR

MENOPUR 1200 IU is provided as a powder in a vial and must be dissolved with **both syringes** with liquid (solvent) before it is injected. The solvent which you will use to dissolve the powder is provided in two pre-filled syringes supplied in the package.

MENOPUR 600 IU is provided as a powder in a vial and must be dissolved with **one syringe** with liquid (solvent) before it is injected. The solvent which you will use to dissolve the powder is provided in a pre-filled syringe supplied in the package.

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.

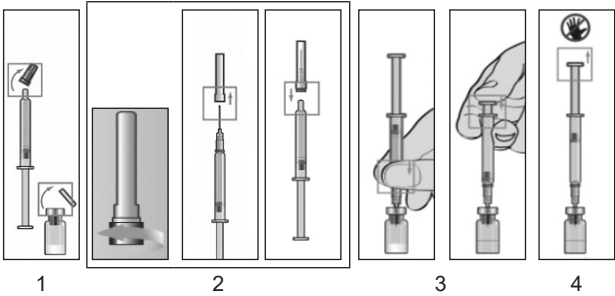
As this vial contains medication for several days of treatment, you need to make sure you only draw up the dose that was prescribed by your doctor. Note that the dose of Menopur you are prescribed is measured in IU. To obtain the correct dose you must use one of the graduated syringes in the package that are marked with IU units of LH and FSH.



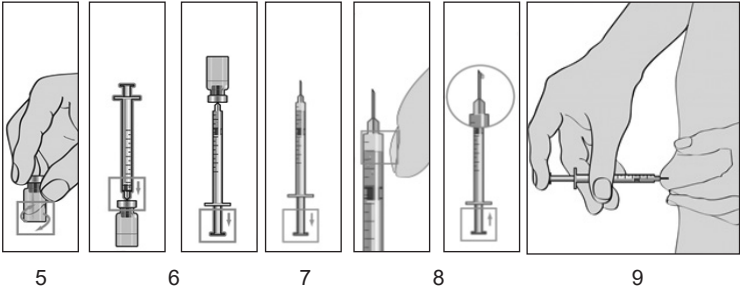
What to do:

1. Remove the cap from the vial of powder and the syringe cap from the syringe with solvent (Figure 1).
2. Firmly attach the thick needle (reconstitution needle) to the syringe with solvent and remove the needle cap (Figure 2).
3. Insert the needle through the center of the rubber stopper of the powder vial and slowly inject all of the solvent. Aim at the vial wall to avoid creating bubbles (Figure 3).

If you are preparing MENOPUR 1200 IU, mix the powder in the vial with the contents of both syringes of solvent before using. After you have injected the content of the first syringe with solvent into the powder vial, gently twist the syringe off the needle, leaving the needle inserted in the vial. Remove the cap from the second syringe with solvent and firmly attach the syringe to the needle in the vial. Slowly inject the solvent; aim at the vial wall to avoid creating bubbles.



4. After adding the solvent from each syringe with solvent to the powder vial a slight over-pressure is created in the vial. Therefore, each time, after you have added the solvent from a syringe, let go of the syringe plunger and allow it rise up by itself for about 10 seconds. This will release the pressure in the vial (Figure 4). Remove the syringe and the needle used to reconstitute the medicine.
5. 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 bubbles to form (Figure 5). **Do not use the solution if it is not clear or if it contains particles.**
6. Take a disposable syringe with pre-attached needle and insert the needle vertically into center of the vial. Turn the vial upside down and draw the prescribed dose (Figure 6).
REMEMBER: This vial contains medication for several days of treatment. You need to make sure you only draw up the dose that was prescribed by your doctor.
Injecting MENOPUR
7. Remove the syringe from the vial and pull the plunger out to draw a small amount of air into the syringe (Figure 7).
8. Gently flick the administration syringe and then push the plunger in carefully until the first drops of solution come out (Figure 8).
9. 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.
10. To inject, pinch the skin produce a fold and insert the needle in one swift motion at 90 degrees to the body. Push the plunger in to inject the solution and then pull the needle out of the skin (Figure 9).
11. 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.
12. For the next injection, repeat steps 6 to 11.
13. Use a new disposable syringe with pre-attached needle each time.



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 using MENOPUR if you experience an allergic reaction that includes the following side effects: itching, skin rashes, itching, 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):

- headache
- nausea
- abdominal pain and swelling
- pelvic pain
- overstimulation of the ovaries resulting in 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 1,000 users):

- vomiting
- discomfort in the stomach
- diarrhea
- fatigue
- dizziness
- 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
- rash

Side effects of unknown frequency:

- allergic reactions
- eyesight disturbances
- 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 in a refrigerator at 2°C-8°C. Do not freeze. Store in the original package to protect from light.

- **After dissolving, store below 25°C for 28 days** but no longer than the expiry date.

Do not freeze, either before or after dissolving.

6. Additional information

In addition to the active ingredients, this medicine also contains:

Powder:

lactose monohydrate, polysorbate 20, sodium phosphate dibasic heptahydrate, phosphoric acid.

Solvent:

metacresol, water for injection.

What the medicine looks like and contents of the pack:

MENOPUR Multidose 600 IU: Each pack of medicine contains a vial of powder, a pre-filled syringe with solvent for reconstitution, a needle for reconstitution, 9 disposable syringes with pre-attached needle.

MENOPUR Multidose 1200 IU: Each pack of medicine contains a vial of powder, 2 pre-filled syringes with solvent for reconstitution, a needle for reconstitution, 18 disposable syringes with pre-attached needle.

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:

MENOPUR multidose 600 IU: 147-66-33326

MENOPUR multidose 1200 IU: 147-67-33343

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