

MENOPUR® 600IU

Powder and solvent for solution for injection
HIGHLY PURIFIED MENOTROPHIN

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, nurse or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What MENOPUR is and what it is used for
2. What you need to know before you use MENOPUR
3. How to use MENOPUR
4. Possible side effects
5. How to store MENOPUR
6. Content of the pack and other information

1. What MENOPUR is and what it is used for

MENOPUR is provided as a powder which must be mixed with liquid (solvent) before it is used. It is given as an injection under the skin.

What MENOPUR is

MENOPUR contains the active substance menotrophin which belongs to a group of medicines called gonadotrophins. Menotrophin is a highly purified mixture of two hormones called follicle stimulating hormone (FSH) and luteinizing hormone (LH). FSH and LH are natural hormones produced in both males and females. They help the reproductive organs to work normally. The FSH and LH in Menopur are obtained from the urine of postmenopausal women.

What MENOPUR is used for

In women, MENOPUR is used to treat infertility in the following two situations:

- To promote the release of eggs from the ovaries (ovulation) in women who are not ovulating including with polycystic ovarian disease and who have not responded to treatment with another medicine called clomiphene citrate.
- To help multiple follicles and therefore eggs to develop in women having in vitro fertilisation (IVF) treatment or other types of ‘assisted conception’. The eggs are then harvested and fertilised outside the body.

In men, MENOPUR is used to treat infertility in the following situation:

- Low sperm count (oligospermia).

2. What you need to know before you use MENOPUR

Before starting treatment with MENOPUR, you and your partner should be evaluated by a doctor for the causes of your fertility problems. In particular you should be checked for the following conditions so that any other appropriate treatment can be given:

- Underactive thyroid or adrenal glands
- High levels of a hormone called prolactin (hyperprolactinemia)
- Tumours of the pituitary gland (a gland located on the base of the brain which produces certain hormones, including growth hormones)
- Tumours 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)

If you know you have any of the conditions listed above, **please tell your doctor before starting treatment with MENOPUR.**

Do not use MENOPUR if:

- You are allergic (hypersensitive) to menotrophin or any of the other ingredients of MENOPUR (listed in Section 6).
- You have a tumour in your pituitary gland.
- You have a tumour in the hypothalamus.

Also, if you are a woman do not use MENOPUR if:

- You have tumours of the womb (uterus), ovaries or breasts.
- You have sacs of fluid known as cysts on your ovaries (ovarian cysts) or enlarged ovaries that are not due to polycystic ovarian disease (a condition that prevents eggs from being released from the ovaries).
- You have bleeding from your vagina for an unknown reason.
- You are having an early (premature) menopause.
- You have certain physical problems in your reproductive organs (womb, fallopian tubes, ovaries or cervix).
- Your womb has been removed (hysterectomy).
- You have fibroid tumours (tumours in your womb that are not cancer).
- You are pregnant or breast-feeding.

Also, if you are a man do not use MENOPUR if:

- You have cancer of your testicles.
- You have prostate cancer.

Do not use MENOPUR if any of the above applies to you. If you are not sure, talk to your doctor, nurse or pharmacist before you start using MENOPUR.

Warnings and precautions

Talk to your doctor or nurse if:

- You get pain or swelling of the stomach (abdomen)
- You get nausea or vomiting
- You get diarrhea
- You gain weight
- You have difficulty in breathing
- You get decreased urination (produce less urine)

Tell your doctor straight away, even if the symptoms develop some days after the last injection has been given. These can be signs of high levels of activity in the ovaries which might become severe.

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

Keeping to your recommended 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).

Some women who have been given infertility treatment with multiple medicines have developed tumours in the ovaries and other reproductive organs. It is not yet known if treatment with hormones like MENOPUR causes these problems.

Blood clot formation inside the blood vessels (veins or arteries) are more likely to occur in women who are pregnant. Infertility treatment can increase the chances of this happening, especially if you are overweight or known with 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

There is no relevant use of MENOPUR in children.

Other medicines and MENOPUR

Tell your doctor if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

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 breast-feeding

MENOPUR should not be used during pregnancy or breast-feeding.

Driving and using machines

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

Important information about some of the ingredients of MENOPUR

MENOPUR contains less than 1 mmol sodium (23 mg) per dose, so it is essentially ‘sodium-free’. MENOPUR also contains lactose (which is a type of sugar). If you have been told by your doctor that you cannot tolerate or digest some sugars (have an intolerance to some sugars), talk to your doctor before using this medicine.

3. How to use MENOPUR

Always use MENOPUR exactly as your doctor or nurse has told you. You should check with your doctor, nurse or pharmacist if you are not sure.

Using MENOPUR

- You will have MENOPUR as an injection under the skin.
- You will either be given MENOPUR by a doctor or nurse or you will be taught how to give it to yourself.
- MENOPUR comes as a dry powder in small bottles (vials).
- Once the dry powder has been mixed with the solvent it can be stored for up to 28 days at room temperature (not more than 25°C).
- This mixed solution can now be used for multiple injections.

The dose and length of your treatment

- The dose, and how long your treatment lasts, depends on why you are using MENOPUR and how well it works.
- Your doctor or nurse will monitor how you respond to your treatment.
- This will help them to work out what dose you need and how long you need to use MENOPUR for.

In women:

i **Women who are not ovulating (not producing eggs):**
Treatment should start within the first 7 days of the menstrual cycle (day 1 is the first day of your period). Treatment should be given every day for at least 7 days.

The starting dose is normally 75-150 IU daily but this may be adjusted depending on your response (up to a maximum of 225 IU). A particular dose should be given for at least 7 days before the dose is changed by your doctor. It is recommended that the dose should be increased by 37.5 IU per adjustment (and not more than 75 IU). The cycle of treatment should be abandoned if there is no response after 3 weeks.

When a good response is obtained a single injection of another hormone called human chorionic gonadotrophin (hCG), at a dose of 5,000 to 10,000 IU, should be given 1 day following the last MENOPUR injection. It is recommended to have sexual intercourse on the day of the hCG injection and the day after. Alternatively, artificial insemination (injection of sperm directly into the womb) may be performed. Your doctor will closely monitor your progress for at least 2 weeks after you have received the hCG injection.

Your doctor will monitor the effect of MENOPUR 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 be instructed to use a barrier method of contraception (e.g. condom) or not have sexual intercourse until your next period has started. For the following cycle your doctor will give you a lower dose of MENOPUR than before.

ii **Women in assisted reproductive technology programs:**
If you are also receiving treatment with a GnRH agonist (a medicine which helps a hormone called Gonadotropin Releasing Hormone (GnRH) to work), MENOPUR should be started approximately 2 weeks after the start of the GnRH agonist therapy.

If you are also receiving treatment with a GnRH antagonist, MENOPUR treatment should be started on day 2 or 3 of the menstrual cycle (day 1 is the first day of your period).

MENOPUR should be given every day for at least 5 days. The initial dose of MENOPUR is normally 150-225 IU. This dose may be increased according to your response to the treatment up to a maximum of 450 IU per day. The dose should not be increased by more than 150 IU per adjustment. Normally treatment should not continue for more than 20 days.

If enough egg sacs are present, you will be given a single injection of a medicine called human chorionic gonadotrophin (hCG) at a dose of up to 10,000 IU to induce ovulation (release of an egg).

Your doctor will closely monitor your progress for at least 2 weeks after you have received the hCG injection.

Your doctor will monitor the effect of MENOPUR 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 be instructed to use a barrier method of contraception (e.g. condom) or not have sexual intercourse until your next period has started. For the following cycle your doctor will give you a lower dose of MENOPUR than before.

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.

INSTRUCTIONS FOR USE

If your doctor has asked you to inject MENOPUR yourself, you should follow the instructions provided below.

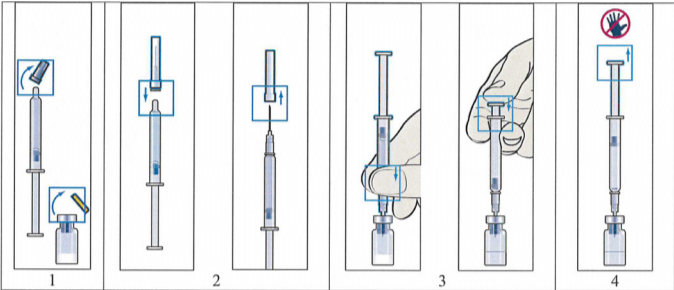
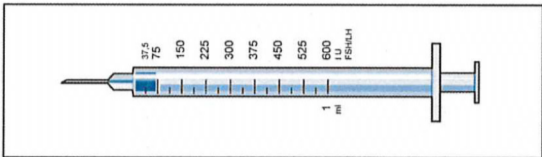
The first injection of MENOPUR should be given under the supervision of a doctor or nurse.

DISSOLVING MENOPUR:

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

Please note: 1 drop of solvent can dissolve the powder immediately, leading to the impression that no powder was present in the vial. Check the vial for powder before mixing the solvent.

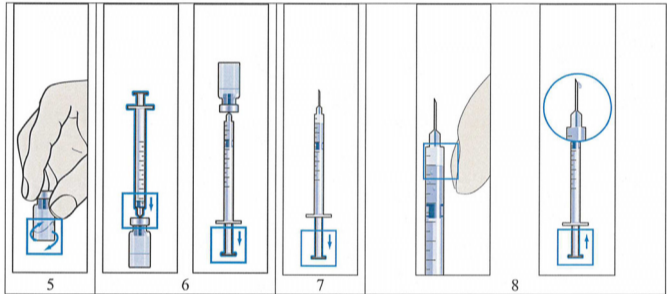
As this vial contains medication for several days of treatment, you need to make sure you only draw up the amount of medication that was prescribed by your doctor. Your doctor has prescribed you a dose of MENOPUR in IU (units). To obtain the correct dose you should use one of the 9 administration syringes graduated in FSH/LH IU units provided.



What to do:

1. Remove the protective cap from the vial of powder and the rubber syringe cap from the pre-filled syringe with solvent (picture 1).
2. Firmly attach the thick needle (**Reconstitution needle**) to the pre-filled syringe with solvent and remove the protective cap from the needle (picture 2).
3. Insert the needle vertically through the centre of the rubber stopper of the powder vial and **slowly inject all** of the solvent to avoid creating bubbles (picture 3).
4. When adding the solvent, a slight over-pressure is created in the vial. Therefore, let go of the syringe plunger to let it rise up by itself for about 10 seconds. This will remove the over-pressure in the vial (picture 4).

Remove the syringe and the needle for reconstitution.



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 (picture 5).

If the solution is not clear or if it contains particles it SHOULD NOT be used.

The vial with powder is now dissolved with one syringe with solvent and ready to use.

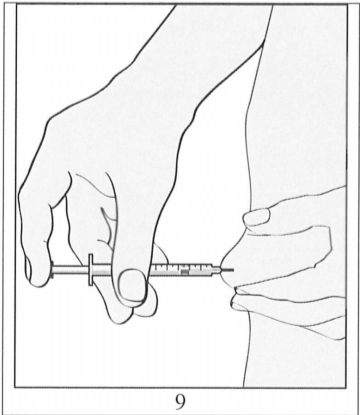
6. Take the administration syringe with pre-fixed needle and insert the needle vertically into centre of the vial. Turn the vial upside down and draw the prescribed dose of MENOPUR into the administration syringe for injection (picture 6).

REMEMBER: As this vial contains medication for several days of treatment, you need to make sure you only draw up the amount of medication that was prescribed by your doctor.

INJECTING MENOPUR

7. Remove the syringe from the vial and draw a small amount of air into the syringe (picture 7).
8. Gently flick the administration syringe so that any air bubbles will be collected in the tip. Depress the plunger carefully until the first drop of fluid comes out (picture 8).

Your doctor or nurse will tell you where to inject yourself (e.g. front of the thigh, stomach (abdomen), etc.). Disinfect the injection site with the provided alcohol pads.



9. 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 gently to inject the solution and then remove the needle (picture 9).
10. After removing the administration syringe, apply pressure to the injection site to stop any bleeding. Gently massaging the injection site will help to disperse the solution under the skin.
11. For the next injection with the reconstituted solution of MENOPUR, repeat steps 6 to 9.

If you use more MENOPUR than you should

If you think you have used too much MENOPUR, tell your doctor, nurse or pharmacist.

If you forget to use MENOPUR

Do not take a double dose to make up for a forgotten dose. Please tell your doctor, nurse or pharmacist.

4. Possible side effects

Like all medicines, MENOPUR can cause side effects, although not everybody gets them.

Side effects that can happen in women:

If you notice any of the following signs, tell your doctor immediately. It may mean that your ovaries have been stimulated too much Ovarian Hyperstimulation Syndrome (OHSS), especially in women with polycystic ovaries and you may need urgent medical treatment.

Symptoms include:

- Nausea (feeling sick)
- Vomiting (being sick)
- Diarrhoea.
- Weight gain.
- Pain or swelling of the stomach

In cases of severe OHSS:

- Fluid build-up in the stomach, pelvis and/or chest
- Difficulty in breathing.
- Decreased urination (producing less urine when you go to the toilet or going to the toilet less often).
- Formation of blood clots in blood vessels (thromboembolism)
- Twisting of ovaries (ovarian torsion)

If you notice any of the above signs, tell your doctor immediately.

Side effects that can happen in both women and men:

STOP USING MENOPUR if you experience allergic (hypersensitivity) reactions including; skin rashes, itching, swelling of the face, lips or throat and difficulty in breathing. If you experience any of these rare side effects, you should contact your doctor or go to the nearest hospital immediately.

Common (may affect up to 1 in 10 people):

- Pain or swelling of the stomach
- 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 (may affect up to 1 in 100 people):

- Vomiting
- Discomfort in stomach
- Diarrhoea
- Fatigue
- Dizziness
- Sacs of fluid within ovaries (ovarian cysts)
- Breast complaints (include breast pain, breast tenderness, breast discomfort, nipple pain and breast swelling)
- Hot flush

Rare (may affect up to 1 in 1,000 people)

- Acne
- Rash

Unknown (the frequency of these reported side effects is not known)

- Eyesight disturbances
- Allergic reactions
- Pain in muscle and joint (e.g. back pain, neck pain and pain in arms and legs)
- Twisting of ovary (ovarian torsion) as a complication of OHSS
- Itching
- Hives

Reporting of side effects

If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme, website: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store MENOPUR

- Keep out of the sight and reach of children.
- Do not use MENOPUR after the expiry date which is stated on the packaging. The expiry date refers to the last day of that month.
- Before reconstitution, store in a refrigerator (2°C - 8°C).
- After reconstitution, the solution may be stored for a maximum of 28 days at not more than 25°C.
- Do not freeze before or after reconstitution.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Content of the pack and other information

What MENOPUR contains

- MENOPUR is a sterile freeze dried powder for injection. The active substance is Highly Purified Menotrophin. Each vial contains 600IU of the active substance, corresponding to 600IU of FSH activity and 600IU of LH activity. After reconstitution, 1ml of the reconstituted solution contains 600IU of Highly Purified Menotrophin.
- The other ingredients for powder are Lactose monohydrate, Polysorbate 20, Sodium phosphate dibasic heptahydrate and Phosphoric acid (concentrated).
- The solvent contains Metacresol and Water for injection.

What MENOPUR looks like and contents of the pack

MENOPUR is a powder and solvent for solution for injection. Supplied as a pack of 1 clear glass vial containing white to off-white lyophilised powder, 1 pre-filled syringe with colourless solvent for reconstitution, 1 needle for reconstitution, 9 alcohol pads and 9 disposable syringes for administration graduated in FSH/LH units with pre-fixed needles.

Marketing Authorisation Holder and Manufacturer.

Marketing Authorisation Holder:

Ferring Pharmaceuticals Ltd.
Drayton Hall, Church Road, West Drayton, UB7 7PS, UK
PL 03194/0106

Manufacturer:

Ferring GmbH
Wittland 11, D-24109 Kiel, Germany

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