

MENOPUR®

Menotrophin HP

75 IU powder and solvent for solution for injection

Consumer Medicine Information

Read all of this leaflet carefully before you start using this medicine.

Keep this leaflet. You may need to read it again. If you have any further questions, ask your doctor or nurse. 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 any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or nurse.

What is in this leaflet

1. What MENOPUR is and what it is used for
2. Before you take MENOPUR
3. How to take MENOPUR
4. Possible side effects
5. How to store MENOPUR
6. Further information

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 or in the muscle.

MENOPUR contains 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 is obtained from the urine of postmenopausal women. It is highly purified, and is then known as menotrophin.

MENOPUR is used to treat female infertility in the following two situations:

- (i) Women who cannot become pregnant because their ovaries do not produce eggs (including polycystic ovarian disease). MENOPUR is used in women who have already been given a medicine called clomiphene citrate to treat their infertility, but this medicine has not helped.
- (ii) Women in assisted reproduction programmes (ART) (including *in vitro* fertilisation/embryo transfer [IVF/ET], gamete intra-fallopian transfer [GIFT] and intracytoplasmic sperm injection [ICSI]). MENOPUR helps the ovaries develop many egg sacs (follicles) where an egg might develop (multiple follicular development).

Before you take MENOPUR

Before starting treatment with MENOPUR, you and your partner should be assessed by a doctor for 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)
- Tumours of the hypothalamus (an area located under the part of the brain called the thalamus)

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

Do not take MENOPUR

- If you are allergic (hypersensitive) to menotrophin or any of the other ingredients of MENOPUR
- If you have tumours of the uterus (womb),

ovaries, breasts, pituitary gland or hypothalamus

- If you have cysts on your ovaries or enlarged ovaries (unless caused by polycystic ovarian disease)
- If you have any physical defects of the uterus (womb) or other sexual organs
- If you suffer from bleeding from the vagina where the cause is not known
- If you have fibroids of the uterus (womb)
- If you are pregnant or breastfeeding
- If you have experienced an early menopause

Take special care with MENOPUR

- If you get pain in the abdomen
- If you get swelling in the abdomen
- If you get nausea
- If you get vomiting
- If you get diarrhoea
- If you gain weight
- If you are having difficulty breathing
- If you get decreased urination

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 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 clots in the 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 if you or someone in your family (blood relative) has had blood clots. Tell your doctor if you think this applies to you.

Taking other medicines

Please tell your doctor if you are taking or have recently taken 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 breastfeeding.

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 chloride (23 mg) per dose, so it is essentially 'sodium-free'.

How to take MENOPUR

Always take MENOPUR exactly as your doctor has told you. You should check with your doctor if you are not sure.

(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. It is recommended that the dose should be increased by 37.5 IU each time (and not more than 75 IU). The cycle of treatment should be abandoned if there is no response after 4 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. Depending on your progress, 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.

(ii) Women in assisted reproduction programmes:

If you are also receiving treatment with a GnRH agonist (a medicine which helps a hormone called Gonadotrophin Releasing Hormone (GnRH) to work), MENOPUR should be started approximately 2 weeks after the start of the GnRH agonist therapy.

In patients not receiving a GnRH agonist, MENOPUR treatment should be started on day 2 or 3 of the menstrual cycle (day 1 is the first day of your period).

Treatment 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. Depending on your progress, 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.

INSTRUCTIONS FOR USE

If your clinic has asked you to inject MENOPUR yourself, you should follow these step-by-step instructions for reconstitution and subcutaneous administration of MENOPUR.

Your doctor or nurse will help you prepare and inject your medication at home.

If you have any questions, call your doctor or nurse.

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

MENOPUR is provided as a powder, and must be dissolved (reconstituted) before it is injected. The solvent (liquid) which you should use to dilute MENOPUR is provided with the powder. This vial contains medication for use in one patient on one occasion only. You need to make sure you only draw up the amount of medication that your doctor has prescribed for you. Your doctor has prescribed for you a dose of MENOPUR in IU (units).

1. Before you start

Wash your hands with antibacterial soap and prepare a clean work surface. Have these supplies ready:

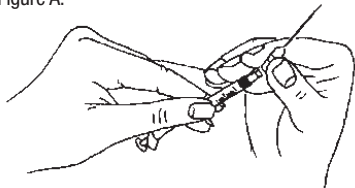
- A vial (or vials) of MENOPUR and a vial of sodium chloride 0.9% (sterile solvent) that is conveniently packaged with your medicine
- A sterile syringe and needles for reconstitution and administration

2. Preparing your medicine by diluting MENOPUR

Remember: Only the sodium chloride (sterile solvent) provided must be used to reconstitute MENOPUR.

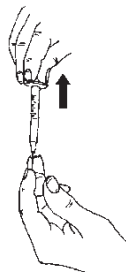
MENOPUR is provided as a powder, and must be diluted before it is injected. The liquid which you should use to dilute MENOPUR is provided with the powder. MENOPUR should only be diluted immediately before use.

Figure A:



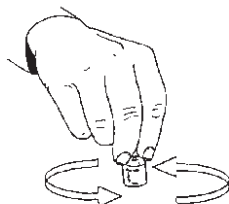
- Firmly attach the long, thick needle (drawing up/reconstitution needle) to the syringe (Figure A).
- Break the liquid ampoule with the dot pointing towards you.
- Insert the needle in the liquid ampoule.

Figure B:



- Draw up all of the liquid from the ampoule into the syringe (Figure B).
- Remove the protective cap from the top of the vial of powder. Do not touch the top of the vial of powder once you have opened it.
- Insert the needle through the rubber top of the powder vial and slowly inject all of the liquid, aiming the sterile solvent at the side of the vial to avoid creating bubbles. Now, leave the empty syringe with the reconstitution needle in the vial.

Figure C:

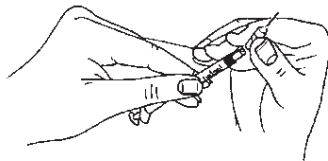


- The powder should quickly dissolve (**within 2 minutes**) to form a clear solution. Gently swirl until the powder is completely dissolved (Figure C). **Do not shake** the vial because this will create air bubbles. *If the solution is not clear or if it contains particles it should not be used.*
- Draw up the solution back into the attached syringe.

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

3. Injecting your medicine

Figure D:



- Once you have your prescribed dose drawn up into the syringe, replace the reconstitution needle with the small, subcutaneous needle by twisting the small needle clockwise onto the syringe (Figure D).
- 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.

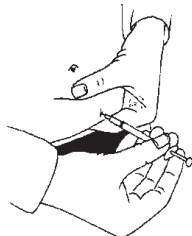
Carefully recap the needle to keep it sterile. The solution is now ready for injection.

Your doctor or nurse will tell you where to inject (e.g. front of the thigh, abdomen, etc).

Remove cap from the needle.

If an uncapped needle EVER comes into contact with anything other than MENOPUR or sterile solvent, do not inject yourself with it. Immediately remove the needle and replace it with a new sterile needle.

Figure E:



- Hold the syringe in one hand. Use your other hand to gently grasp a fold of skin in the injection site area between thumb and index finger. Hold the syringe at a right angle to the skin like a dart and quickly insert the needle all the way into the skin fold. Depress the plunger of the syringe with a steady motion until all the fluid is injected beneath the skin (Figure E).

Release the skin fold and pull the needle straight out.

Recap the needle and discard the syringe and the needle into a disposal container.

After removing the syringe, if any bleeding should occur, simply place a small piece of gauze over the injection site and apply gentle pressure to stop the bleeding. Gently massaging the injection site will help to disperse the solution under the skin.

- Do not put used items into normal domestic waste; these should be disposed of appropriately.

If you forget to take MENOPUR or take more MENOPUR than you should, please tell a nurse or doctor.

Possible Side Effects

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

Treatment with MENOPUR may cause **high levels of activity in the ovaries**, especially in women with polycystic ovaries. Symptoms include: **pain in the abdomen, swelling in the abdomen, nausea, vomiting, diarrhoea, weight gain, difficulty breathing and decreased urination.**

As complications to high levels of activity in the ovaries, blood clots and twisting of an ovary might occur. If you experience any of these symptoms contact your doctor immediately, even if they develop some days after the last injection has been given.

Allergic (hypersensitivity) reactions may occur when using this medicine. Symptoms of these reactions might include: **rash, itching, swelling of the throat and difficulty breathing.** If you experience any of these symptoms, contact your doctor immediately.

The following common side effects affect between 1 and 10 of every 100 patients treated:

- Pain in the abdomen
- Headache
- Nausea
- Swelling in the abdomen
- Pelvic pain
- Overstimulation of the ovaries (high levels of activity)
- Injection site pain and reactions (redness, bruising, swelling and/or itching)

If you experience one or more of these side effects, or any other problems, please tell a nurse or doctor.

How to store MENOPUR

Do not store above 25°C. Do not freeze.

Store in the original container in order to protect from light.

Keep out of the reach and sight of children.

Do not use MENOPUR after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

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.

Further information

What MENOPUR contains

The active substance is highly purified menotrophin (human menopausal gonadotrophin, hMG) corresponding to follicle stimulating hormone activity FSH 75 IU and luteinizing hormone activity LH 75 IU.

The other ingredients in the powder are:

- Lactose monohydrate
- Polysorbate 20
- Sodium hydroxide

The ingredients in the solvent are:

- Water
- Sodium chloride
- Hydrochloric acid

What MENOPUR looks like and contents of the pack

MENOPUR is a powder and solvent for solution for injection.

The carton contains five or ten clear glass vials which contain a light powder. The carton also contains an equal number of clear glass ampoules containing a colourless solvent.

Not all pack sizes may be marketed.

Distributor

Pharmaco (NZ) Ltd
4 Fisher Crescent
Mt Wellington
Auckland 1060

This leaflet was prepared in August 2012.
(Core PIL 2009/05 & Aust #12118-v3C)

MENOPUR CMI LEAFLET

Dimensions:

180.0 x 300.0mm

Job Number

LH2468 Menopur CMI Leaflet v3.pdf

Date: 31/8/12

Black