MENOPUR® multidose 600IU
MENOPUR® multidose 1200IU

Powder and solvent for solution for injection
Menotrophin HP 600IU and 1200IU

Read the entire leaflet carefully before 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 or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or nurse. This includes any possible side effects not listed in the leaflet

What is in this leaflet:

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.

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® are obtained from the urine of postmenopausal women. The active ingredient is highly purified, and is known as menotrophin.

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

i. Anovulation, including polycystic ovarian disease (PCOD), in women who have been unresponsive to treatment with clomiphene citrate.

ii. Women in Assisted Reproductive Technology, (ART) programmes (including in vitro fertilization / embryo transfer [IVF/ET], gamete intra-fallopian transfer [GIFT] and intracytoplasmic sperm injection [ICSI]). MENOPUR® helps the ovaries to develop many egg sacs (follicles) where an egg might develop (multiple follicular developments).

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 appropriate treatment can be given:

- Underactive thyroid or adrenal glands
- High levels of prolactin hormone (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 use MENOPUR®

- If you are allergic to menotrophin or any of the other ingredients of MENOPUR® (6. Content of the pack and other information)
- If you have tumours of the womb (uterus), ovaries, breasts or parts of the brain like pituitary gland or hypothalamus
- If you have sacs of fluid known as cysts on your ovaries (ovarian cysts) or enlarged ovaries (unless caused by PCOD)
- If you have any physical defects of the womb or other sexual organs
- If you suffer from unknown causes of vaginal bleeding
- If you have fibroids (benign tumors) of the womb (uterus)
- If you are pregnant or breastfeeding
- If you have experienced an early menopause

Warnings and precautions

Talk to your doctor if you experience:

- Pain in the abdomen
- Swelling in the abdomen
- Nausea, vomiting and/or diarrhea
- Weight gain
- Difficulty breathing
- Decreased urination.

Tell your doctor immediately, if the symptoms develop at any time during the treatment. These can be signs of Ovarian hyperstimulation syndrome, OHSS (high levels of activity in the ovaries which might become severe).

If you stop using MENOPUR® you might still experience these symptoms. Please contact your doctor immediately if any of these symptoms persist.

Your doctor will normally arrange regular **ultrasound scans** and sometimes **blood tests** to monitor your body's response towards the 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).

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) 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.

Elderly
There is no relevant use of MENOPUR® in elderly population.

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.

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

3. HOW TO USE MENOPUR®
Always use MENOPUR® exactly as directed by your doctor. Check with your doctor if you are not sure.

i. Anovulation, including polycystic ovarian disease (PCOD), in women who have been unresponsive to treatment with clomiphene citrate.

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. Dose may be increased according to your response to the treatment up to a maximum of 225 IU per day. 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 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.

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. 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 any instructions they provide.

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

MENOPUR® is provided as a powder in a vial, and must be dissolved with one syringe with solvent before it is injected. The solvent which you should use to dissolve MENOPUR® is provided in a prefilled syringe in the package.

MENOPUR® multidose **600 IU** must be dissolved with **one pre-filled syringe** with solvent before use.

MENOPUR® multidose **1200 IU** must be dissolved with **two pre-filled syringe** with solvent before use.

After dissolving the powder with the solvent this vial **contains medication for several days of treatment**, therefore, 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.

To do this:

1. Remove the protective cap from the vial of powder and the rubber cap from the pre-filled syringe with solvent.

2. Firmly attach the needle (reconstitution needle) to the pre-filled syringe with solvent and remove the protective cap from the needle.

3. Insert the needle through the rubber top of the powder vial and slowly inject **all** of the solvent to avoid

creating bubbles. Remove the syringe and the needle for reconstitution.

For MENOPUR® multidose 1200IU, after a few seconds from the initial reconstitution, gently remove the syringe from the needle with a twist, leaving the needle in the vial. Remove the rubber cap from the second pre-filled syringe with solvent and firmly attach the syringe to the needle fixed in the vial. Slowly inject **all** of the solvent to avoid creating bubbles. Remove the syringe and the needle for reconstitution.

4. The powder should quickly dissolve (within 2 minutes) to form a clear solution. Although this normally happens when only few drops of solvent have been added, the entire amount of the solvent should be added. To help the powder dissolve, swirl the solution. **Do not shake** as this will cause air bubbles to form. *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.

5. Take the administration syringe with pre-fixed needle and insert the needle into the vial. Turn the vial upside down and draw the prescribed dose of MENOPUR® into the administration syringe for injection.

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

6. Gently flick the administration syringe so that any air bubbles will be collected in the tip. Push the syringe carefully until the first drop of fluid comes out. Your doctor or nurse will tell you where to inject (e.g. front of the thigh, abdomen etc.). Before injection, disinfect the injection site.

7. 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 administration syringe. 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. Do not put used items into normal domestic waster; these should be disposed of appropriately.

8. For next injection from the already dissolved MENOPUR® solution, repeat steps 5 to 7.

If you take more MENOPUR® than you should
Please tell a nurse or doctor.

If you forget to take MENOPUR®
Do not take a double dose to make up for a forgotten dose. Please tell a nurse or doctor.

4. POSSIBLE SIDE EFFECTS
Like all medicines, MENOPUR® can cause side effects, although not everybody gets them.

Symptoms of Allergic reaction (hypersensitivity) might include **rash, itching, swelling of the throat and difficulty in breathing.**

The following common side effects (affects between 1 to 10 of every 100 patients treated):
- Pain in the abdomen
- Headache
- Nausea / vomiting
- Swelling in the abdomen
- Pelvic pain
- Overstimulation of the ovaries resulting into high levels of activity (OHSS)
- Local reactions at the injection site (such as pain, redness, bruising, swelling and/or itching)

The following uncommon side effects (affects between 1 to 100 of every 1,000 patients treated):
- Vomiting
- Discomfort in abdomen
- Diarrhoea
- Fatigue
- Dizziness
- Ovarian cysts
- Breast complaints (include breast pain, breast tenderness, breast discomfort, nipple pain and breast swelling)
- Hot flush

The following rare side effects (affects between 1 to 1000 of every 10,000 patients treated):
- Acne
- Rash

In addition to above the following side effects were seen after MENOPUR® was marketed
(frequency of these side effects is unknown):
- Eyesight disturbances
- Fever
- Feeling sick
- Allergic reactions
- Increase in weight
- Pains 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 increased activity of ovaries due to overstimulation
- Itching
- Hives
- Blood clots as a complication of increased activity of ovaries due to overstimulation

If you get any side effects, talk to your doctor or nurse. This includes any side effects not listed in this leaflet.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting)

5. HOW TO STORE MENOPUR

Keep this medicine out of sight and reach of children.
Prior to reconstitution store in a refrigerator (2°C – 8°C). Do not freeze.
After reconstitution, the solution may be stored for a maximum of 28 days at not more than 2°C – 8°C.
The reconstituted solution should not be administered if it contains particles or is not clear.
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. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicine you no longer use. These measures will help protect the environment.

6. CONTENT OF THE PACKS AND OTHER INFORMATION

What MENOPUR contains

MENOPUR® multidose 600 IU:
The active substance is highly purified menotrophin (human menopausal gonadotrophin, HMG) corresponding to 600IU follicle stimulating hormone (FSH) bioactivity and 600IU luteinizing hormone (LH) bioactivity.
After reconstitution, 1 ml of the reconstituted solution contains 600 IU highly purified menotrophin.

MENOPUR® multidose 1200 IU:
The active substance is highly purified menotrophin (human menopausal gonadotrophin, HMG) corresponding to 1200IU follicle stimulating hormone (FSH) bioactivity and 1200IU luteinizing hormone (LH) bioactivity.
After reconstitution with the 2 ml solvent, 1 ml of the reconstituted solution contains 600 IU highly purified menotrophin.

The other ingredients in the powder are:
Lactose monohydrate
Polysorbate 20
Sodium phosphate dibasic heptahydrate (as buffer agents and for pH adjustment)
Phosphoric acid (for pH adjustment)

The ingredients in the solvent are:
Water for injection
Metacresol

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

What MENOPUR® looks like and contents of the pack

MENOPUR® is a powder and solvent for solution for injection.

MENOPUR® multidose 600 IU
The product is supplied as a pack of 1 vial of powder, 1 pre-filled syringe with solvent for reconstitution, 1 needle for reconstitution and 9 disposable syringes for administration graduated in FSH/LH units with pre-fixed needles.

MENOPUR® multidose 1200 IU
The product is supplied as a pack of 1 vial of powder, 2 pre-filled syringes with solvent for reconstitution, 1 needle for reconstitution and 18 disposable syringes for administration graduated in FSH/LH units with pre-fixed needles.

MARKETING AUTHORISATION HOLDER

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