

Menopur®

Powder and solvent for solution for injection

Human menopausal gonadotrophin

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Menopur.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Menopur against the benefits he/she expects it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

What Menopur is used for

Menopur contains highly purified human menopausal gonadotrophin (hMG), also known as menotrophin, as the active ingredient. It is obtained from the urine of post-menopausal women.

hMG is a mixture of three hormones with follicle stimulating hormone (FSH) activity and luteinising hormone (LH) activity found naturally in humans.

Menopur belongs to a class of medicines called gonadotrophins.

Menopur is used to treat infertility (reproduction related conditions) in women.

Menopur is used in women who are not ovulating (not producing eggs). It helps women become pregnant by

stimulating the ovarian follicles to release an egg.

Menopur is also used to stimulate the ovarian follicles in women undergoing Assisted Reproductive Technology (ART) such as IVF/ET (in vitro fertilisation/embryo transfer), GIFT (gamete intra-fallopian transfer) and ICSI (intracytoplasmic sperm injection) to help them become pregnant.

Your doctor will be able to talk to you about your specific fertility problem.

Menopur is given only by or under the supervision of your doctor.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

This medicine is available only with a doctor's prescription.

This medicine is not expected to affect your ability to drive a car or operate machinery.

Before you use Menopur

The active ingredient in this preparation is extracted from human urine. Therefore, the risk of transmission of a pathogen (known or unknown) cannot be completely excluded.

When you must not use it

Do not use Menopur if you have or have had an allergy to:

- any medicine containing menotrophin or human menopausal gonadotrophin
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not use Menopur if:

- you have tumours of the uterus (womb), ovaries, breasts, pituitary gland or hypothalamus
- you have cysts on your ovaries or enlarged ovaries (unless caused by polycystic ovarian disease)
- you have any physical defects of the uterus (womb) or other sexual organs
- you suffer from bleeding from the vagina where the cause is not known
- you have fibroids of the uterus (womb)
- you are pregnant
- you are breastfeeding.

Do not use Menopur after the expiry date printed on the pack.

Do not use Menopur if the packaging is torn or shows signs of tampering.

If you are not sure whether you should have this medicine, talk to your doctor.

Before you use it

Tell your doctor if you have allergies to:

- any other medicines
- any other substances such as foods, preservatives or dyes.

Tell your doctor if you have or have had any medical conditions, especially the following:

- problems with genital organs
- adrenal problems
- thyroid problems
- diabetes, or a family history of diabetes
- primary ovarian failure
- polycystic ovarian syndrome (PCOS)
- ovarian hyperstimulation syndrome (OHSS)
- any problems with your liver, kidneys or other organs
- you are obese (BMI > 30 kg/m²) or have a condition that increases your risk of having blood clots (thrombophilia), or if you or someone in your family (blood relative) has had blood clots. Blood clot formation inside the blood vessels (veins or arteries) is more likely to occur in women who are pregnant. Infertility treatment can increase the chances of this happening, especially in women with these pre-existing conditions.

If you have not told your doctor about any of the above, tell him/her before you are given Menopur.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

If Menopur is used at the same time as clomiphene citrate the effect on the ovaries may be increased.

How Menopur is used

How it is used

Menopur is given as an injection under the skin (subcutaneous), usually near the stomach.

If your doctor or nurse decides you can give the injections yourself, they will teach you the injection technique.

Do not self-inject until you are sure of how to do it.

Follow all instructions given to you by your doctor carefully.

Please see the leaflet supplied with Menopur for detailed instructions on how it is to be reconstituted and administered.

How much is used

The dose of Menopur will depend on your condition and will be determined by your doctor.

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. This dose may be increased according to your response to the treatment up to maximum of 225 IU per day. A particular dose should be given for at least 7 days before the dose is changed. 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), should be given 1 day following the last Menopur injection. It is recommended that you 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.

Women undergoing Assisted Reproductive Technology (ART):

If you are also receiving treatment with a GnRH agonist (a medicine that acts like a hormone called Gonadotrophin Releasing Hormone, GnRH), Menopur should be started approximately 2 weeks after the start of the GnRH agonist therapy.

In patients receiving 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).

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. 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) 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.

How often is it given

The length of treatment varies with each patient being treated. Your doctor will be able to answer this question.

It is possible to have more than one treatment cycle of Menopur.

Overdose

As your doctor will tell you the dose of Menopur, it is very unlikely that you will receive too much.

In women, hyperstimulation of the ovaries, known as ovarian hyperstimulation syndrome (OHSS) is a rare but potentially serious complication of infertility therapy and can be the result of excessive doses of Menopur. Without proper hospital management this condition may even be fatal.

The initial symptoms may consist of abdominal pain, abdominal swelling and/or nausea and vomiting.

While you are using Menopur

Take special care with Menopur if:

- you feel pain in the abdomen or in the pelvic region
- you get swelling in the abdomen
- you experience nausea
- you experience vomiting
- you develop diarrhoea
- you gain weight
- you feel tired
- you experience difficulty breathing
- you notice decreased urination.

Tell your doctor straight away, even if the symptoms develop some days after the last injection has been given. This can be a sign of high levels of activity in the ovaries.

Therefore, symptoms 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 will reduce your chances of getting these symptoms.

Things you must do

Tell your doctor immediately if you become pregnant while using Menopur.

Tell your doctor if you have abnormal vaginal bleeding while using Menopur.

Be sure to keep all your doctor's appointments so your progress can be checked.

Your doctor will normally arrange for you to have ultrasound scans and do some blood and other tests from time to time to check on your progress and detect any unwanted side effects.

Tell any other doctors, dentists, and pharmacists who are treating you that you are using Menopur.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are using Menopur.

If you are going to have surgery, tell the surgeon or anaesthetist that you are using Menopur.

Things to be careful of

Menopur should not normally interfere with your ability to drive or operate machinery.

Pregnancy risks

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

- ectopic pregnancy (pregnancy outside of the womb). Women who have a history of fallopian tube disease are also at increased risk of ectopic pregnancy whether they conceive naturally or following IVF
- miscarriage

- multiple pregnancy (twins, triplets, etc)
- congenital malformations (physical defects present in baby at birth).

Some women who have been given multiple medicines for 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.

Side effects

Tell your doctor or nurse or pharmacist as soon as possible if you do not feel well after you have Menopur.

This medicine helps most people with infertility, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or nurse or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- local reaction around the injection site such as redness, itchiness, tenderness, pain or discomfort, warmth, burning or stinging or swelling
- breast swelling, breast pain, tenderness or discomfort (including nipple pain)
- generalised rash or itchiness
- acne
- headache
- fever
- hot flush
- dizziness
- tiredness

- generally feeling unwell
- problems with your eyes
- pain in muscles or joints, including back, neck and/or extremities.

These may be mild or rare side effects and are usually short-lived.

Tell your doctor as soon as possible if you notice any of the following:

- swelling in your hands, feet or ankles.

The above list includes serious side effects which may require medical attention.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you experience any of the following.

- sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing
- abdominal or pelvic pain, abdominal swelling, nausea, vomiting and/or diarrhoea (initial symptoms of ovarian hyperstimulation syndrome)
- Menopur sometimes stimulates the ovaries too much. This is called ovarian hyperstimulation syndrome (OHSS) and can be a serious medical problem. OHSS may cause pelvic pain, diarrhoea and weight gain, or breathing problems. It may also make you urinate less. In cases of severe OHSS accumulation of fluid in abdomen, pelvis and/or chest cavity and twisting of ovaries (ovarian torsion) have been reported as rare complications. In rare cases, patients with this problem have had serious lung problems. This includes fluid in the lungs, trouble breathing, and worsening of asthma
- blood clots and strokes.

These are very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After using Menopur

Storage

Keep Menopur where children cannot reach it.

Keep Menopur in the original pack until it is time for it to be used.

Store Menopur 600 IU and 1200 IU in a refrigerator (2 to 8°C). Do not freeze. After reconstitution, the solution may be stored for up to 28 days.

Disposal

If you are self-injecting, you should discard all sharps into a disposal unit.

If you have any Menopur that has expired or is left over from your treatment refer this to your clinic.

Product description

What it looks like

Menopur 600 IU

The product is supplied as a pack containing one vial of powder, one pre-filled syringe with solvent for reconstitution and one needle for reconstitution. Disposable alcohol pads and single-use administration syringes (graduated in FSH/LH units with pre-fixed needles) are supplied separately.

Menopur 1200 IU

The product is supplied as a pack containing one vial of powder, two pre-filled syringes with solvent for reconstitution and one needle for reconstitution. Disposable alcohol pads and single-use administration syringes (graduated in FSH/LH

units with pre-fixed needles) are supplied separately.

Ingredients

Menopur 600 IU

Each vial of Menopur contains human menopausal gonadotrophin corresponding to follicle stimulating hormone activity (FSH) 600 IU and luteinizing hormone activity (LH) 600 IU as the active ingredient.

Menopur 1200 IU

Each vial of Menopur contains human menopausal gonadotrophin corresponding to follicle stimulating hormone activity FSH 1200 IU and luteinizing hormone activity LH 1200 IU as the active ingredient.

The other ingredients in the powder are:

- lactose monohydrate
- polysorbate 20
- sodium phosphate
- phosphoric acid.

The other ingredients in the solvent are:

- meta-cresol and
- water for injections.

This medicine does not contain sucrose, gluten, tartrazine or any other azo dyes.

Sponsor:

Menopur is distributed in Australia by:

Ferring Pharmaceuticals Pty Ltd
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20 Bridge Street, Pymble NSW
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