

MENOPUR®

Powder and solvent for solution for injection

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using MENOPUR?

MENOPUR is used to treat infertility (reproduction related conditions) in women. It contains the active ingredient human menopausal gonadotrophin. For more information, see Section [1. Why am I using MENOPUR?](#) in the full CMI.

2. What should I know before I use MENOPUR?

Do not use MENOPUR if you have ever had an allergic reaction to human menopausal gonadotrophin, gonadotrophins, or to any of the ingredients listed at the end of the CMI, see Section [7. Product details](#).

There are several circumstances in which a person should not use this medicine or may need to use it with caution. It is important to understand if any of these apply to you before using MENOPUR.

Talk to your doctor if you have any other medical conditions or take any other medicines.

For more information, see Section [2. What should I know before I use MENOPUR?](#) in the full CMI.

3. What if I am taking other medicines?

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

Some medicines may interfere with MENOPUR and affect how it works. For more information, see Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use MENOPUR?

- **You should only use MENOPUR under the supervision of a doctor experienced in the treatment of infertility.**
- Always use this medicine exactly as your doctor has told you. You should check with your doctor if you are unsure. Your doctor will determine your dose of MENOPUR depending on your condition.
- Before using MENOPUR, you must be educated on how to prepare the injection solution and how to perform injections. Your first injection must be supervised by a trained health practitioner.

More instructions can be found in Section [4. How do I use MENOPUR?](#) in the full CMI and in the 'Patient Instructions for Use' leaflet inside the carton.

5. What should I know while using MENOPUR?

Things you should do	<ul style="list-style-type: none">• Tell any doctor, dentist or pharmacist you visit that you are using MENOPUR.• Be sure to keep all your doctor's appointments so your progress can be checked regularly.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine or change the dose without talking to your doctor.• Do not give this medicine to anyone else even if they have the same condition as you.
Looking after your medicine	<ul style="list-style-type: none">• Store MENOPUR in a refrigerator (2°C to 8°C). Do not freeze.• Always store MENOPUR in the original pack until it is time to use it.

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| | <ul style="list-style-type: none">• After mixing powder with solvent, the solution may be stored in a refrigerator for up to 28 days. |
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For more information, see Section [5. What should I know while using MENOPUR?](#) in the full CMI.

6. Are there any side effects?

All medicines can have side effects. Most of them are minor and temporary but some may need medical attention.

Tell your doctor if you experience any side effects.

Common side effects include skin reactions at the site where MENOPUR has been injected, such as redness, pain and swelling.

Pain and/or swelling in the abdomen or pelvic region, nausea, vomiting, diarrhoea, weight gain, having difficulty breathing and/or reduced urination may be a sign of too much activity in the ovaries and may require urgent medical attention in hospital. For more information, see Section [6. Are there any side effects?](#) in the full CMI.

MENOPUR®

Powder and solvent for solution for injection

Active ingredient: *human menopausal gonadotrophin*

Consumer Medicine Information (CMI)

This leaflet provides important information about using MENOPUR. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using MENOPUR.**

Where to find information in this leaflet:

- [1. Why am I using MENOPUR?](#)
- [2. What should I know before I use MENOPUR?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use MENOPUR?](#)
- [5. What should I know while using MENOPUR?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using MENOPUR?

MENOPUR is used to treat infertility (reproduction related conditions) in women. It belongs to a class of medicines called gonadotrophins.

MENOPUR contains the active ingredient highly purified human menopausal gonadotrophin (hMG), which originates from the urine of postmenopausal women.

hMG is a mixture of hormones found naturally in humans, with follicle stimulating hormone (FSH) bioactivity and luteinising hormone (LH) bioactivity. The primary contributor of the LH bioactivity is human chorionic gonadotrophin (hCG).

hCG is a hormone naturally present in the urine of postmenopausal and pregnant women. Extracted hCG from the urine of pregnant women may be used to balance the total LH bioactivity.

MENOPUR is used to stimulate the ovaries to grow and develop egg sacs ('follicles').

MENOPUR is used to stimulate the follicles in women undergoing Assisted Reproductive Technology (ART) procedures to help them become pregnant. ART procedures include IVF/ET (*in vitro* fertilisation/embryo transfer), GIFT (gamete intrafallopian transfer) and ICSI (intracytoplasmic sperm injection).

MENOPUR is also used in women who are not ovulating (not releasing eggs) naturally and who have not responded to another medicine called clomiphene citrate.

2. What should I know before I use MENOPUR?

Warnings

Do not use MENOPUR if:

- you are allergic to human menopausal gonadotrophin, gonadotrophins, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- you are pregnant or breastfeeding
- you have cancer of the uterus (womb), ovaries, or breasts
- you have a tumour of the pituitary gland or hypothalamus
- you have enlarged ovaries or cysts on your ovaries not caused by polycystic ovarian disease
- you have bleeding from the vagina where the cause is not known
- your ovaries have failed
- you have malformations of the sexual organs, which make a normal pregnancy impossible
- you have fibroids, or tumours, of the uterus (womb), which make a normal pregnancy impossible.

Tell your doctor if you:

- have or have had any other medical conditions, especially the following:

- adrenal problems
 - thyroid problems
 - high prolactin levels in the blood
 - blood clots, a history of blood clots, or any condition that puts you at risk of blood clots
 - polycystic ovarian syndrome (PCOS)
 - ovarian hyperstimulation syndrome (OHSS)
 - fallopian tube disease
 - kidney or liver disease.
- take any medicines for any other condition.

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.

Your doctor will assess you and your partner's fertility. This may include tests for other medical conditions, including medical conditions which may interfere with your ability to become pregnant. If necessary, other medical conditions may be treated before starting infertility treatments, including the use of MENOPUR.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Do not use MENOPUR if you are pregnant or breastfeeding.

It may affect your developing baby if you use it during pregnancy. Talk to your doctor immediately if you become pregnant while using MENOPUR.

Pregnancy risks

- The risk of a pregnancy outside of the womb (ectopic pregnancy) may be higher after assisted reproduction than if you conceive naturally. If you have a history of tubal disease, you have an increased risk of ectopic pregnancy.
- Compared to natural conception, the frequency of pregnancy loss is higher in patients undergoing fertility treatments.
- Multiple pregnancy, more than one baby at a time, carries greater risks for mothers and babies. In patients undergoing ART procedures, the risk of multiple pregnancy is related to the number of embryos replaced, their quality and your age. Your doctor will monitor your response to treatment to minimise the chance of multiple pregnancies.
- There may be a slightly increased risk of birth defects in women using assisted reproductive technologies. This may be due to increased maternal age, genetic factors, multiple pregnancies or the procedures.

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.

Ovarian hyperstimulation syndrome (OHSS)

Some people have an exaggerated response to hormones used in ART, including MENOPUR. This may lead to ovarian hyperstimulation syndrome (OHSS). This is when your follicles develop too much, causing your ovaries to swell and become painful.

Talk to your doctor if you have:

- abdominal pain, discomfort or swelling
- nausea
- vomiting
- diarrhoea
- weight gain
- difficulty in breathing
- decreased urination.

Blood clots

Tell your doctor if you or a family member have or have had blood clots or signs of blood clots (e.g. pain, warmth, redness, numbness or tingling in the arm or leg).

Blood clots are more likely to form inside your blood vessels when you are pregnant. This is more likely if you have had treatment to help you become pregnant and:

- you are overweight (BMI > 30 kg/m²)
- you have a condition that increases your risk of having blood clots ('thrombophilia')

- you or someone in your family (blood relative) has had blood clots.

3. What if I am taking other medicines?

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

Some medicines may interfere with MENOPUR and affect how it works.

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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect MENOPUR.

4. How do I use MENOPUR?

Treatment with MENOPUR should be started under the supervision of a specialist doctor experienced in the treatment of infertility.

How much to use

Always use this medicine exactly as your doctor has told you. You should check with your doctor if you are unsure.

The dose of MENOPUR and the length of treatment will be determined by your doctor depending on your condition.

Women who are not ovulating (not releasing eggs) without treatment:

- The initial dose is normally 75-150 IU daily.
- Your doctor may change the dose, according to your response to the treatment, up to a maximum of 225 IU per day.
- The same dose should be given for at least 7 days before the dose is changed by the doctor.
- Your doctor will monitor the effect of MENOPUR treatment. The cycle of treatment should be stopped if there is no response after 4 weeks.

Women undergoing Assisted Reproductive Technology (ART):

- The initial dose of MENOPUR is normally 150-225 IU.
- Your doctor may change the dose, 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.

When to use MENOPUR

Women who are not ovulating (not releasing eggs) without treatment:

- 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.

- 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.

- If enough follicles have developed, you will be given a single injection of a medicine called human chorionic gonadotrophin (hCG) to stimulate the final maturation of the eggs in the follicles prior to collection and fertilisation.
- 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 you have responded too strongly to MENOPUR, 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 to inject MENOPUR

- MENOPUR is to be injected under the skin of your abdomen using a new area of the abdomen on each occasion.
- Before using MENOPUR, you must be educated on how to prepare the injection solution and how to perform injections.
- Your first injection must be supervised by a trained health practitioner.
- Step-by-step instructions on how to prepare and inject MENOPUR are provided in the 'Patient Instructions for Use' leaflet inside the carton.

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

If you forget to use MENOPUR

If you forget an injection or are not sure what to do, contact your doctor or nurse immediately for advice.

Do not inject a double dose to make up for the dose you missed.

If you use too much MENOPUR

MENOPUR may cause hyperstimulation of the ovaries known as ovarian hyperstimulation syndrome (OHSS). OHSS is a rare but potentially serious complication of infertility treatment and could be fatal without proper management in hospital. The initial symptoms may consist of abdominal pain, abdominal swelling and/or nausea and vomiting.

If you think that you have used too much MENOPUR, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre **(by calling 13 11 26)**, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using MENOPUR?

Things you should do

Call your doctor straight away if you:

- feel pain in the abdomen or pelvic region
- notice swelling in the abdomen
- experience nausea (feeling sick) or vomiting
- develop diarrhoea
- gain weight
- have trouble breathing
- notice you are urinating less.

Tell your doctor straight away if you notice any of the above symptoms, 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 known as OHSS and the symptoms could become severe.

If these symptoms become severe, treatment with MENOPUR should be stopped and you should receive urgent medical attention in hospital.

Keeping to your recommended dose and careful monitoring of your treatment will reduce your chances of getting these symptoms.

You should also contact your doctor right away if you:

- become pregnant
- have unusual vaginal bleeding.

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 doctor, dentist or pharmacist you visit that you are using MENOPUR. If you are going to have surgery, tell the surgeon or anaesthetist that you are using MENOPUR.

Things you should not do

- Do not stop using this medicine or change your dose without talking to your doctor.
- Do not give this medicine to anyone else even if they have the same condition as you.

Driving or using machines

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

Be careful before you drive or use any machines or tools until you know how MENOPUR affects you.

Drinking alcohol

Tell your doctor if you drink alcohol.

It is unknown how drinking alcohol will affect MENOPUR.

Looking after your medicine

- Keep MENOPUR in a refrigerator at a temperature of 2°C to 8°C. Do not freeze.
- Always store MENOPUR in the original pack until it is time to use it.
- After mixing powder with solvent, the solution may be stored in a refrigerator at a temperature of 2°C to 8°C for up to 28 days. After 28 days, the vial containing any unused medicine should be discarded.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Follow the instructions in the carton on how to take care of your medicine properly.

Keep it where young children cannot reach it.

When to discard your medicine

Discard MENOPUR if it has been opened and reconstituted for more than 28 days.

Do not use this medicine after the expiry date.

Once you have injected MENOPUR, do not re-use the needles and syringes. Discard the used needles and syringes into an approved, puncture-resistant sharps container and keep it out of reach of children. Never put

used needles and syringes into your normal household rubbish bin.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor, nurse or pharmacist if you have any further questions about side effects.

Side effects

Side effects	What to do
<p>Common side effects (affect more than 1 in 100 users):</p> <ul style="list-style-type: none">• headache• reactions at the injection site:<ul style="list-style-type: none">◦ redness◦ itchiness◦ tenderness◦ pain or discomfort	<p>These side effects are not usually serious but can become serious.</p> <p>Seek immediate medical care if you have any concerns.</p>

Side effects	What to do
<ul style="list-style-type: none"> ○ warmth or burning ○ stinging ○ swelling. <p>Uncommon side effects (affect less than 1 in 100 users):</p> <ul style="list-style-type: none"> ● breast swelling, pain (including nipple pain), tenderness or discomfort ● hot flush ● dizziness ● tiredness. <p>Rare side effects (affect less than 1 in 1,000 users):</p> <ul style="list-style-type: none"> ● generalised rash or itchiness ● acne. <p>Frequency unknown:</p> <ul style="list-style-type: none"> ● fever ● generally feeling unwell ● problems with your eyes ● pain in muscles or joints including back, neck and/or extremities such as the hands or feet. 	

Serious side effects

Serious side effects	What to do
<p>Allergic reaction (unknown frequency):</p> <ul style="list-style-type: none"> • rash, itching or hives on the skin • swelling of the face, lips, tongue or other parts of the body • shortness of breath, wheezing or difficulty breathing. <p>Ovarian hyperstimulation syndrome (OHSS):</p> <ul style="list-style-type: none"> • Common signs of OHSS: <ul style="list-style-type: none"> ◦ stomach pain and/or swelling ◦ pelvic pain ◦ nausea or vomiting ◦ diarrhoea. • Rare complications of OHSS: <ul style="list-style-type: none"> ◦ rapid weight gain (due to fluid accumulation) 	<p>Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects, even if a few days have passed since your last injection, or you have stopped using MENOPUR.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> ○ shortness of breath ○ passing less urine ○ blood clots (thromboembolism) ○ twisting of ovaries (ovarian torsion). 	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What MENOPUR contains

Active ingredient (main ingredient)	human menopausal gonadotrophin
Other ingredients (inactive ingredients)	<i>Powder:</i> <ul style="list-style-type: none">• lactose monohydrate• polysorbate 20• dibasic sodium phosphate heptahydrate• phosphoric acid. <i>Solvent:</i> <ul style="list-style-type: none">• metacresol• water for injections.

Do not use this medicine if you are allergic to any of these ingredients.

MENOPUR 600 IU: Contains human menopausal gonadotrophin corresponding to 600 IU follicle stimulating hormone (FSH) bioactivity and 600 IU luteinising hormone (LH) bioactivity.

MENOPUR 1200 IU: Contains human menopausal gonadotrophin corresponding to 1200 IU follicle stimulating hormone (FSH) bioactivity and 1200 IU luteinising hormone (LH) bioactivity.

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

What MENOPUR looks like

MENOPUR is supplied in packs containing medicine powder (vial), solvent for reconstitution and needle for reconstitution. Disposable, single-use administration syringes (graduated in FSH/LH units with pre-fixed needles) are supplied separately.

Inspect the medicine vial before use to ensure that a white powder cake is visible. The cake may seem to disappear after the needle tip enters the rubber top, but you can continue with the reconstitution as long as the cake was visible on first inspection.

MENOPUR 600 IU pack contains:

1 x vial of powder, 1 x pre-filled syringe with solvent for reconstitution and 1 x needle for reconstitution
(AUST R 161984)

MENOPUR 1200 IU pack contains:

1 x vial of powder, 2 x pre-filled syringes with solvent for reconstitution and 1 x needle for reconstitution
(AUST R 161985)

Who distributes MENOPUR

MENOPUR is distributed in Australia by:

Ferring Pharmaceuticals Pty Ltd

Suite 2, Level 1, Building 1

20 Bridge Street, Pymble NSW 2073

This leaflet was prepared in November 2025.

AU-MR-2200002 v4.0