

MENOPUR[®]

HIGHLY PURIFIED MENOTROPHIN
Powder for Injection

Patient 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, 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 any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, nurse or pharmacist.

In this leaflet:

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

1. What Menopur is and what it is used for

What Menopur is

Menopur contains a medicine called menotrophin. This is a mixture of hormones obtained from the urine of women who have passed the menopause.

- The dose of these hormones is given in International Units (IU).
- Each bottle (vial) contains the equivalent of 75 IU of FSH (follicle stimulating hormone) and 75 IU of LH (luteinising hormone).

Menopur helps reproductive organs to work normally in both women and men. A fertility specialist should supervise your treatment.

What Menopur is used for

In women, Menopur is used for:

- Infertility caused by eggs not being produced properly in the ovaries (anovulatory infertility). It works by helping follicles (which contain eggs) to mature in the ovaries.
- IVF (in vitro fertilisation) and other types of 'assisted conception'. It works by helping multiple follicles and eggs to develop. The eggs are then harvested and fertilised outside the body.

In men, Menopur is used for:

- Low sperm count (oligospermia).

2. Before you use 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 (a gland located on the base of the brain which produces certain hormones, including growth hormones).

- You have a tumour in a part of your brain called the hypothalamus (part of the brain which controls the conditions within your body including body temperature and blood pressure).
- You have high levels of a hormone called prolactin (hyperprolactinaemia).

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

- You have tumours of your womb (uterus), ovaries or breasts.
- You have cysts on your ovaries or enlarged ovaries that are not due to polycystic ovary syndrome (a condition that prevents eggs from being released from the ovaries).
- You have bleeding from your vagina for an unknown reason.
- You have primary ovarian failure (a condition in which the ovaries do not function properly).
- You have blocked fallopian tubes, unless you are having IVF or ICSI (intracytoplasmic sperm injection).
- 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.

Take special care

Check with your doctor or nurse before using this medicine if:

- You have had infertility treatment in the past.
- You or someone in your family has had blood clots. This is because treatment with Menopur may increase the risk of having a clot. Pregnancy also increases the risk of having clots.

If any of the above applies to you (or if you are not sure), talk to your doctor, nurse or pharmacist before using Menopur.

Pregnancy and breast-feeding

If you are already pregnant or breast-feeding, you must not use Menopur.

Tests before you start treatment

Before you start treatment with Menopur, your doctor will normally do tests to check the following:

Men and women:

- Your thyroid and adrenal glands are working properly.
- You do not have tumours of the pituitary gland or hypothalamus.

Women only:

- Your ovaries are working properly.
- You do not have higher than normal blood levels of a hormone called prolactin.

Important information about some of the ingredients of Menopur

Menopur 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.

Menopur is not recommended for children or elderly people.

Using Menopur

- You will have Menopur as an injection into a muscle or 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 salt solution (solvent) it should be used straight away.

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.

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:

Infertility (to help follicles to mature):

- If you are having periods, your treatment will start within the first 7 days of your menstrual cycle.
- You may use Menopur daily for up to 3 weeks.
- Or, you may use Menopur every other day for 6 days (three doses in total).

'Assisted conception' such as IVF:

- The usual dose is 75 to 300 IU each day.
- Your doctor will decide how long you need to use Menopur for.

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.

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

If you think you have missed a dose, 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 and you may need urgent medical treatment. This side effect is common (affects less than 1 in 10 people).

- Feeling sick.
- Pain or swelling of the tummy.
- Being sick.
- Weight gain.
- Diarrhoea.
- Difficulty breathing.
- Feeling more thirsty than usual.
- Producing less urine when you go to the toilet or going to the toilet less often.

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 reactions including; itching, skin rashes, swelling of the face, lips or throat, difficulty in breathing, wheeziness, chest tightness or coughing. If you experience any of these rare side effects, you should contact your doctor or go to the nearest hospital immediately.

Common (affects less than 1 in 10 people):

- Headache.
- Pain or inflammation where the injection was given.

Uncommon (affects less than 1 in 100 people):

- Blood clots in the veins, usually of the leg (deep vein thrombosis).

Very rare (affects less than 1 in 10,000 people):

- If Menopur is used for a long time, your body may make antibodies which can stop the treatment from working.

If treatment with Menopur results in pregnancy

The following are more likely to happen in women who have had fertility treatment than in women who have got pregnant (conceived) naturally:

- Being pregnant with more than one baby. This carries an increased risk of problems for the mother during the pregnancy and at or around the time of birth.
- The fertilised egg implanting outside the womb (ectopic pregnancy). This is more likely if you have had tubal disease in the past (a condition where the fallopian tubes are blocked or damaged).
- Miscarriage or abortion.
- A slightly higher risk of your baby being born with physical defects.

Your doctor will be able to discuss this with you before you start treatment.

If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, nurse or pharmacist.

5. How to store Menopur

- Keep out of the reach and sight of children.
- Do not use Menopur after the expiry date which is stated on the packaging.
- Store below 25°C.
- Protect from light.
- 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. Further information

What Menopur contains

- Menopur is a sterile freeze dried powder for injection. The active substance is menotrophin BP. Each vial contains 75 IU of the active substance.
- The other ingredients are lactose, sodium hydroxide and hydrochloric acid.
- The solvent (Sodium Chloride Solution for Injections 0.9% w/v) contains water for injection, sodium chloride and hydrochloric acid.

What Menopur looks like and contents of the pack

Menopur is supplied in boxes of 1, 5 and 10 vials of Menopur powder for injection with the corresponding number of 1, 5 and 10 ampoules of 1ml Solvent (Sodium Chloride Solution for Injection 0.9%w/v). The solvent is used to dissolve the powder before it is injected.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation Holder for Menopur and Sodium Chloride Solution for Injections 0.9%w/v Ferring Pharmaceuticals Ltd., Drayton Hall, Church Road, West Drayton, UB7 7PS, (UK).

Menopur is manufactured by Dr. Rentschler Biotechnologie GmbH, Erwin-Rentschler-Straße 21, D-88471 Laupheim, Germany.

Sodium Chloride Solution for Injection 0.9% w/v is manufactured by Weimer Pharma GmbH, Im Steingerust 30, D-76437 Rastatt, Germany.

Menopur® PL 03194/0074

Sodium Chloride Solution for Injections 0.9%w/v PL 03194/0060

This leaflet was last revised August 2017.

Menopur is a registered Trademark.

