

MENOPUR[®]

HIGHLY PURIFIED MENOTROPHIN

Patient Information

Remember

Only a doctor can prescribe this medicine. It should never be given to anyone except the person it has been prescribed for. It may harm them even if they have the same symptoms.

Please read this information carefully before starting treatment with the medicine.

This leaflet does not contain the complete information, so if you have any questions or there is anything you are unsure about, ask your doctor or pharmacist.

ABOUT YOUR MEDICINE

Menopur is a sterile freeze dried powder for injection. It contains the active ingredient menotrophin BP 75 Units and the inactive carrier, lactose and sodium hydroxide and hydrochloric acid to adjust the pH. It is supplied in boxes of 5 or 10 vials of Menopur packaged together with 5 or 10 ampoules of Solvent 1 ml (Sodium Chloride Solution for Injections 0.9%w/v) used to dissolve the powder before it is injected. The solvent contains water for injection with sodium chloride to adjust the concentration and hydrochloric acid to adjust the acidity of the solution to values that are suitable for injection.

Product licence holder: Ferring Pharmaceuticals Ltd., The Courtyard, Waterside Drive, Langley, Berkshire SL3 6EZ.

The manufacturer of Menopur is Dr. Rentschler Biotechnologie GmbH, Erwin-Rentschler-Straße 21, D-88471 Laupheim, Germany and the solvent is Weimer Pharma GmbH, Im Steingerüst 30, D-76437 Rastatt, Germany.

Menotrophin contains follicle stimulating hormone and luteinising hormone, two natural hormones produced in both males and females, and is obtained from the urine of post menopausal women. These hormones help to maintain the normal function of the reproductive organs in both males and females.

Menopur should only be used for the management of infertility under the supervision of a specialist.

USES

Menopur is used:

In females:

- To induce follicular maturation during the management of infertility caused by the failure of the ovaries to produce eggs (anovulatory infertility)
- In in vitro fertilisation (test tube) procedures or other assisted conception techniques to induce multiple follicular development.

In males:

- To treat poor sperm count (oligospermia).

BEFORE STARTING TREATMENT WITH YOUR MEDICINE

Do not use Menopur if:

- you have tumours of the pituitary gland or hypothalamus
- you are allergic to the active substance or any other ingredients in Menopur
- you have high levels of a hormone called prolactin (hyperprolactinaemia).

In addition:

Females should not use Menopur if:

- you have tumours of the uterus, ovaries or breasts
- you have cysts on the ovaries, or enlarged ovaries not due to polycystic ovary syndrome (a condition preventing eggs from being released from the ovaries)
- you are a pregnant or nursing mother
- you have unexplained bleeding from the vagina
- your ovaries are not functioning properly
- you have blocked fallopian tubes, unless undergoing IVF (in vitro fertilisation) or ICSI (intracytoplasmic sperm injection)
- you have premature menopause
- you have a physical defect of your reproductive organs (uterus, tubes, ovaries and/or cervix)
- your uterus has been removed
- you have fibroid tumours (non cancerous tumours of the uterus)

Males should not use Menopur if:

- you have tumours of the testes
- you have prostate cancer

Before you begin treatment with Menopur, your doctor will normally check the following:

- your thyroid and adrenal glands are working properly
- your ovaries are working properly
- you do not have tumours of the pituitary gland or hypothalamus
- you do not have higher than normal blood levels of a hormone called prolactin, which can affect infertility.

Tell your doctor or nurse if you have or have had any of the following:

- previous treatment for infertility
- a personal or family history of having blood clots. Treatment with Menopur may increase the risk of having a clot(s) and pregnancy itself increases the risk of having clots.

USING YOUR MEDICINE

Depending on which condition you are being treated for, the appropriate dose is administered by intramuscular injection (into a muscle) or subcutaneous injection (just under the skin). There are many different dosage schemes but common doses include:

In the female:

To induce follicular maturation:

In menstruating patients treatment should be started within the first 7 days of the menstrual cycle. Menopur may be given daily for up to 3 weeks to provide a dose of 75 to 150 units until there is an adequate response. Alternatively, three equal doses of Menopur, each providing 225 to 375 units may be given on alternate days.

To induce multiple follicular development:

Stimulation of follicular growth is produced by Menopur in daily doses of 75 to 300 units. Treatment is continued until an adequate response is obtained.

In the male:

Treatment of Oligospermia:

Menopur is given in a dose of 75 or 150 units two or three times weekly. Treatment is normally continued for at least 3 or 4 months.

If you think you have missed a dose or you have been given too much Menopur, please tell a nurse or doctor.

Once the Menopur dry powder has been mixed with the solvent it should be used straight away.

Menopur is not recommended for children or elderly patients.

POSSIBLE SIDE EFFECTS

The use of Menopur may cause harmful over stimulation of the ovaries. If you experience pain or swelling of the abdomen, weight gain, difficulty breathing, increased thirst, decreased urine output, nausea, vomiting and diarrhoea, tell your doctor immediately.

Like all medicines this medicine can also have side effects.

Commonly reported side effects include over stimulation of the ovaries, headache, nausea and vomiting, pain and/or swelling of the abdomen, pain and/or inflammation at the injection site.

Uncommonly reported side effects include deep vein thrombosis (clot formation in the veins, usually of the leg).

Very rarely, allergic reactions have been reported after treatment with products containing gonadotrophins e.g. Menopur.

In very rare cases, the long term use of menotrophin containing products can lead to the formation of antibodies, making treatment ineffective.

If you experience one or more of these side effects, or any other undesirable effects, please inform your doctor or nurse.

If treatment with Menopur results in pregnancy:

- there is a possibility that pregnancy from treatment with Menopur may result in multiple births (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
- there is a risk of an ectopic pregnancy (where a fertilised egg implants outside the uterus) if you have had a history of tubal disease
- in patients undergoing infertility treatment, there is a greater risk of miscarriage or abortion than in the general population. There may be a slightly higher risk of your baby being born with physical defects.

STORING YOUR MEDICINE

Menopur should be stored at a temperature not greater than 25°C. It must also be protected from light. Do NOT use Menopur if it is past the expiry date on the packaging.

If you are unsure about the storage ask your pharmacist. It is best to return all old and unused medication to your pharmacist for safe disposal.

All medicines should be stored away from children.

PLEASE DO NOT THROW THIS LEAFLET AWAY UNTIL THE MEDICINE IS FINISHED AS IT MAY BE NEEDED AGAIN

Menopur® PL 03194/0074

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

This leaflet was revised in 03/2008

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FERRING
PHARMACEUTICALS