

Prescribing Information: Menopur® (menotrophin), Menopur® 75 IU, 150 IU, 600 IU and 1200 IU powder and solvent for solution for injection.

Please consult the full Summary of Product Characteristics (SPC) before prescribing.

Name of Product: Menopur 75 IU. Composition:

Each vial with powder contains highly purified menotrophin (human menopausal gonadotrophin, HMG) containing 75 IU human follicle stimulating hormone (FSH) and 75 IU human luteinising hormone (LH) activity. Supplied with diluent ampoules of sodium chloride solution for injections 0.9% w/v. **Menopur 150 IU. Composition:**

Each vial with powder contains HMG corresponding to 150 IU FSH and 150 IU LH. Supplied with diluent ampoules of sodium chloride solution for injections 0.9% w/v. **Menopur 600 IU. Composition:**

Each vial with powder contains HMG corresponding to 600 IU FSH and 600 IU LH activity. Supplied with a pre-filled syringe of solvent. **Menopur 1200 IU. Composition:**

Each vial with powder contains HMG corresponding to 1200 IU FSH and 1200 IU LH activity. Supplied with two pre-filled syringes of solvent.

Indications: 1. *Women undergoing controlled ovarian stimulation (COS) to induce multiple follicular development in patients undergoing assisted conception.* 2. Anovulation, including polycystic ovarian disease (PCOD) in women who have been unresponsive to treatment with clomiphene citrate.

Dosage: Subcutaneous (s.c.) or intra-muscular injection for 75/150IU, s.c. for 600/1200IU. *Controlled ovarian stimulation:* The recommended initial dose is 150 to 225 IU daily and can be increased to a maximum of 450 IU daily. For 75/150 IU, up to three powder vials can be dissolved with one ampoule of solvent. When an optimal response is obtained, Menopur is stopped and an injection of 5,000-10,000IU of human chorionic gonadotrophin (hCG) is given to induce follicular maturation. *Anovulation:* The recommended initial dose is 75-150 IU daily and can be increased to a maximum of 225IU. The recommended dose increment is 37.5 IU per adjustment (not more frequently than every 7 days) and should not exceed 75 IU. **Contraindications:** Tumours of the pituitary or hypothalamic glands; ovarian, uterine or mammary carcinoma; pregnancy and lactation; gynaecological haemorrhage of unknown aetiology; ovarian cysts or enlarged ovaries not due to polycystic ovarian disease; hypersensitivity to the active substance or any of the excipients. In the following situations treatment outcome is unlikely to be favourable, therefore Menopur should not be used: primary ovarian failure, malformation of sexual organs and fibroid tumours of the uterus incompatible with pregnancy; structural abnormalities in which a satisfactory outcome cannot be expected. **Special Warnings and Precautions:** Should only be used by physicians thoroughly familiar with infertility problems and their management; the first injection of Menopur should be performed under direct

medical supervision. The following should be excluded as the cause of infertility before Menopur therapy is initiated: hypothyroidism, adrenocortical deficiency, hyper-prolactinemia. Patients undergoing COS may be at an increased risk of developing ovarian hyperstimulation syndrome (OHSS) in view of the excessive oestrogen response and multiple follicular development. This may be minimised by careful monitoring and withholding hCG. Aspiration of all follicles prior to ovulation may reduce the incidence of OHSS. Information on multiple and ectopic pregnancy, pregnancy wastage, reproductive system neoplasms, congenital malformation and thromboembolic events is covered in the full SPC. **Side Effects:** *Common:* headache, abdominal pain, abdominal distension, nausea, ovarian hyperstimulation, pelvic pain, injection site reactions. *Uncommon:* vomiting, abdominal discomfort, diarrhoea, fatigue, dizziness, ovarian cyst, breast complaints. *Rare:* acne, rash. **Nature and Contents of Containers: Menopur 75 IU;** Cartons of 10 vials of powder together with the corresponding number of solvent ampoules for reconstitution. **Menopur 150 IU;** Cartons of 10 vials of powder with the corresponding number of solvent ampoules for reconstitution. **Menopur 600 IU;** Cartons of 1 vial of powder, 1 pre-filled syringe with solvent for reconstitution, 1 needle for reconstitution, 9 disposable syringes for administration graduated in FSH/LH units with pre-fixed needles. **Menopur 1200 IU;** Cartons of 1 vial of powder, 2 pre-filled syringes with solvent for reconstitution, 1 needle for reconstitution, 18 disposable syringes for administration graduated in FSH/LH units with pre-fixed needles. **Marketing Authorisation Numbers: Menopur 75 IU;** PL 03194/0074. Solution for Injections 0.9% w/v PL 03194/0060. **Menopur 150 IU;** PL 03194/0109. **Menopur 600 IU;** PL 03194/0106. **Menopur 1200 IU;** PL 03194/0107. **Basic NHS Price: Menopur 75 IU;** 10 vials £180.18. **Menopur 150 IU;** 10 vials £360.36. **Menopur 600 IU;** £144.14. **Menopur 1200 IU;** £288.29. **Marketing Authorisation Holder:** Ferring Pharmaceuticals Ltd., Drayton Hall, Church Road, West Drayton, UB7 7PS. **Legal Category:** POM. **Date of Preparation:** June 2022. Menopur is a registered trademark. **Job Code:** UK-MR-2200007

Adverse events should be reported.

Reporting forms and information can be found at
www.mhra.gov.uk/yellowcard
Adverse events should also be reported to Ferring
Pharmaceuticals Ltd.

Tel: 0800 111 4126

Email: **medical.uk@ferring.com**