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 of powder contains highly purified menotrophin (human menopausal gonadotrophin, HMG) corresponding to 75 IU human follicle stimulating hormone (FSH) and 75 IU human luteinising hormone (LH) activity. **Menopur 150 IU. Composition**: Each vial of powder contains HMG corresponding to 150 IU FSH and 150 IU LH activity. **Menopur 600 IU. Composition**: Each vial of powder contains HMG corresponding to 600 IU FSH and 600 IU LH activity. **Menopur 1200 IU**. **Composition**: Each vial of powder contains HMG corresponding to 1200 IU FSH and 1200 IU LH activity. **Indications:** 1. *Women undergoing controlled ovarian hyperstimulation (COS) to* induce multiple follicular development in patients undergoing assisted reproductive technologies. 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. only for 600/1200IU. *Controlled ovarian hyperstimulation:* If using down-regulation with GnRH agonist, start Menopur approximately 2 weeks after start of agonist treatment. If using down-regulation with GnRH antagonist, start Menopur on day 2 or 3 of the menstrual cycle. Recommended initial dose is 150-225 IU daily for at least the first 5 days of treatment. Based on clinical monitoring (ultrasound alone or with estradiol levels), adjust subsequent dosing according to response but do not exceed more than 150 IU per adjustment. Maximum daily dose should not be higher than 450 IU daily and dosing beyond 20 days is not recommended. When a suitable number of follicles have reached an appropriate size, administer a single injection of 5000-10000 IU hCG to induce final follicular maturation. Monitor closely for at least 2 weeks after hCG administration. If excessive response to Menopur, stop treatment and withhold hCG and advise patient to use a barrier contraception or refrain from coitus until next menstrual bleeding has started. *Anovulation*: Start Menopur within initial 7 days of menstrual cycle. Recommended initial dose is 75-150 IU daily which should be maintained for at least 7 days. Based on clinical monitoring (ultrasound alone or with measurement of estradiol levels), adjust subsequent dosing according to response. Dose adjustments should not be made more frequently than every 7 days. Recommended dose increment is 37.5 IU per adjustment and should not exceed 75 IU. Maximum daily dose should not be higher than 225 IU. If no adequate response after 3 weeks of treatment, abandon cycle and recommence treatment at a higher starting dose than in the abandoned cycle. When an optimal response is obtained, stop Menopur. Administer a single injection of 5000-10000 IU hCG 1 day after the last Menopur injection. Patient is recommended to have coitus on the day of and the day following hCG administration. Alternatively perform intrauterine insemination. If excessive response to Menopur, stop treatment and withhold hCG. Patient should use barrier contraception or refrain from coitus until next menstrual bleeding. Recommence next treatment at a lower dose than in previous cycle. **Contraindications:** Tumours of pituitary gland or hypothalamus; 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 active substance or excipients. As unlikely to be favourable outcome, do not use Menopur in: primary ovarian failure, malformation of sexual organs or 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; perform first Menopur injection under direct medical supervision. Before starting therapy, evaluate patients for: hypothyroidism, adrenocortical deficiency, hyper-prolactinemia, pituitary or hypothalamic tumours and treat appropriately. Use lowest effective dose. Monitor carefully as patients may experience ovarian enlargement or develop hyperstimulation. OHSS: Monitor for symptoms. If urinary oestrogen levels exceed 540 nmol/24 hours or if plasma 17 beta-estradiol levels exceed 3000 pmol/L or if any steep rise in values, immediately discontinue Menopur and withhold hCG. Adherence to recommended Menopur dose, regimen of administration and careful monitoring will minimise incidence of ovarian hyperstimulation and multiple pregnancy. In ART, aspiration of all follicles prior to ovulation may reduce hyper stimulation occurrence. If severe OHSS occurs, stop gonadotrophin treatment, hospitalise and treat patient. Multiple pregnancy: Incidence of multiple pregnancies increased in patients undergoing ovulation induction with gonadotrophins compared with natural conception. To minimise risk, carefully monitor ovarian response. Advise patient of potential risk of multiple birth before starting treatment. Pregnancy wastage: Higher incidence of miscarriage or abortion if undergoing stimulation of follicular growth for ART procedures than normal population. Ectopic pregnancy: History of tubal disease increases risk of ectopic pregnancy. Prevalence of ectopic pregnancy after IVF reported as 2-5% compared to 1-1.5% in general population. Reproductive system neoplasms: Not yet established whether gonadotrophin treatment increases baseline risk in infertile women. Congenital malformation: Prevalence after ART may be slightly higher than after spontaneous conceptions. Thromboembolism: Women with risk factors e.g. personal or family history, severe obesity, thrombophilia may have an increased risk of venous or arterial thromboembolism - weigh benefits against risk. **Interactions:** Expected that concomitant use of Menopur and clomiphene citrate may enhance follicular response. When using a GnRH agonist for pituitary desensitisation, a higher dose of Menopur may be necessary to achieve adequate follicular response. **Pregnancy/breastfeeding:** Contraindicated. **Side Effects:** *Common:* headache, abdominal pain, abdominal distension, nausea, ovarian hyperstimulation syndrome (OHSS), pelvic pain, injection site reactions. *Uncommon:* vomiting, abdominal discomfort, diarrhoea, fatigue, dizziness, ovarian cyst, breast complaints, hot flush. *Rare:* acne, rash. Unknown frequency: visual disorders, hypersensitivity reactions. musculoskeletal pain, ovarian torsion, pruritus, urticaria. **Marketing Authorisation Numbers: Menopur 75 IU;** PL 03194/0074. **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:** August 2023. Menopur is a registered trademark. **Job Code:** UK-MR-2300042

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**