PRODUCT INFORMATION

NAME OF THE MEDICINE
MENOPUR® (human menopausal gonadotrophin), powder and solvent for solution for injection

MENOPUR 600 IU (600 IU/mL after reconstitution): Each vial with powder contains highly purified menotrophin (human menopausal gonadotrophin, hMG) corresponding to follicle stimulating hormone activity FSH 600 IU and luteinising hormone activity LH 600 IU.

MENOPUR 1200 IU (600 IU/mL after reconstitution): Each vial with powder contains highly purified menotrophin (human menopausal gonadotrophin, hMG) corresponding to follicle stimulating hormone activity FSH 1200 IU and luteinising hormone activity LH 1200 IU.

Human Chorionic Gonadotrophin (hCG), a naturally occurring hormone in postmenopausal urine, is present in MENOPUR and is the main contributor of the LH activity.

CAS number: 9002-68-0

DESCRIPTION
Menotrophin (hMG, human Menopausal Gonadotrophin) is described in both the British Pharmacopoeia (BP) and the United States Pharmacopeia (USP). Highly purified hMG drug substance is obtained from the urine of menopausal/postmenopausal women. Highly purified hMG is an almost white or slightly yellow powder containing not less than 2000 IU of FSH and LH activity per mg of substance. It is soluble in water. The three gonadotrophins Luteinising Hormone (LH), human Chorionic Gonadotrophin (hCG) and Follicle-Stimulating Hormone (FSH) have been identified in the drug substance.

Powder and solvent for solution for injection.
Appearance of powder: white to off-white lyophilisation cake.
Appearance of solvent: clear colourless solution.

Excipients:
Powder: Lactose, polysorbate 20, sodium phosphate dibasic, phosphoric acid
Solvent: meta-Cresol, Water for injections.

PHARMACOLOGY
Pharmacotherapeutic group: Gonadotrophins
ATC code: G03G A02

Human Chorionic Gonadotrophin (hCG), a naturally occurring hormone in postmenopausal urine, is present in MENOPUR and is the main contributor of the LH activity.
Menotrophin, which contains both FSH and LH activity, induces ovarian follicular growth and development as well as gonadal steroid production in women who do not have primary ovarian failure. FSH is the primary driver of follicular recruitment and growth in early folliculogenesis, while LH is important for ovarian steroidogenesis and is involved in the physiological events leading to the development of a competent pre-ovulatory follicle. Follicular growth can be stimulated by FSH in the total absence of LH, but the resulting follicles develop abnormally and are associated with low oestradiol levels and inability to luteinise to a normal ovulatory stimulus.

In line with the action of LH activity in enhancing stereoidogenesis, oestradiol levels associated with treatment with MENOPUR are higher than with recombinant FSH preparations in downregulated IVF/ICSI cycles. This issue should be considered when monitoring patients' response based on oestradiol levels. The difference in oestradiol levels is not found when using low-dose ovulation induction protocols in anovulatory patients.

**Pharmacokinetics**

The pharmacokinetic profile of the FSH in MENOPUR has been documented. After 7 days of repeated dosing with 150 IU MENOPUR in downregulated healthy female volunteers, maximum plasma FSH concentrations (baseline-corrected) (mean ± SD) was 8.9 ± 3.5 IU/L for the SC administration. Maximum FSH concentrations were reached within 7 hours. After repeated administration, FSH was eliminated with a half-life (mean ± SD) of 30 ± 11 hours for the SC administration. Although the individual LH concentration versus time curves show an increase in the LH concentration after dosing with MENOPUR, the data available were too sparse to be subjected to a pharmacokinetic analysis. In a bioequivalence study (CS05) utilising a single dose of 450 IU of MENOPUR in downregulated healthy female volunteers, serum hCG was below the assay limit of detection at baseline in all subjects, consistent with their non-pregnant pre-menopausal state, and rose following administration of MENOPUR in a time profile similar to that of FSH.

Menotrophin is excreted primarily via the kidneys.

The pharmacokinetics of MENOPUR in patients with renal or hepatic impairment has not been investigated.

**CLINICAL TRIALS**

**Anovulatory infertility**

CS002 was a prospective randomised clinical trial in 184 women with WHO Group II anovulatory infertility failing to ovulate or conceive on clomiphene citrate. Ovarian stimulation was achieved using a low-dose step-up protocol. The study was designed to document the non-inferiority of MENOPUR SC versus a recombinant FSH preparation (GONAL-F) SC with respect to ovulation rate after one cycle of gonadotrophin treatment.

MENOPUR was demonstrated to be non-inferior to rFSH with respect to ovulation rate (Table 1). In addition to the PP and ITT analyses yielding identical conclusions, the result of the sensitivity analysis adjusting for age and BMI was consistent, supporting the robustness of the conclusion drawn from the primary analysis.
Significantly fewer intermediate-sized follicles were observed in the MENOPUR group (P<0.05). The singleton live birth rate was comparable between the two groups. The frequency of ovarian hyperstimulation syndrome and/or cancellation due to excessive response was 2.2% with MENOPUR and 9.8% with rFSH (P=0.058).

**Table 1: Efficacy outcomes of anovulation in study CS002 (one cycle of treatment)**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>PP</th>
<th>ITT</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>MENOPUR SC</td>
<td>rFSH SC</td>
</tr>
<tr>
<td>Ovulation rate (%)</td>
<td>85.7</td>
<td>85.5</td>
</tr>
<tr>
<td>Lower limit of 95% CI*</td>
<td>-11%</td>
<td>-12%</td>
</tr>
</tbody>
</table>

*Pre-specified non-inferiority limit was -20%

**Controlled ovarian hyperstimulation**

Study 0399E (European and Israeli Study Group trial, EISG), was a Phase 3, randomised study in 727 infertile females undergoing ovarian stimulation to produce multiple follicles for IVF and embryo transfer (IVF/ET) after pituitary suppression with a GnRH agonist. The study was designed to demonstrate non-inferiority of MENOPUR with respect to a recombinant FSH preparation (GONAL-F). The pre-specified non-inferiority limit was -10%. Randomisation was stratified by insemination technique (conventional IVF vs ICSI). Efficacy was assessed based on the primary efficacy parameter of ongoing pregnancy. The initial daily dose of gonadotrophin was 225 IU SC for 5 days. Thereafter the dose was individualised according to each patient’s response, up to a maximum of 450 IU/day for a total maximum duration of stimulation of 20 days. Treatment outcomes are summarised in Table 2. The result confirmed that MENOPUR is non inferior to rFSH with respect to ongoing pregnancy rates. Rates of clinical and biochemical pregnancies were also comparable, as were overall safety results.

**Table 2: Efficacy Outcomes for IVF study 0399E (one cycle of treatment)**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>MENOPUR SC (n = 373)</th>
<th>rFSH SC (n = 354)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ongoing pregnancy</td>
<td>87 (23.3%)</td>
<td>73 (20.6%)</td>
</tr>
<tr>
<td>Clinical pregnancy</td>
<td>98 (26.3%)</td>
<td>78 (22.0%)</td>
</tr>
</tbody>
</table>

CS003 (menotrophin versus recombinant FSH (GONAL-F) in vitro fertilisation trial, MERIT), was a Phase 3, randomised study in 731 women undergoing IVF following downregulation with a GnRH agonist. The study was designed as a superiority study (convertible to non-inferiority with a pre-specified non-inferiority limit of an odds ratio of 0.65) with respect to the primary outcome measure, ongoing pregnancy rate. Randomisation was stratified by age. The starting dose of gonadotrophin was 225 IU SC for the first 5 days. Thereafter the dose could be adjusted individually, according to the subject’s follicular response. Treatment outcomes are summarised in the table below. The odds ratio of ongoing pregnancy was 1.25 in favour of MENOPUR (95% CI 0.89-1.75). Non-inferiority of MENOPUR with respect to rFSH was demonstrated (Table 3).

**Table 3: Efficacy Outcomes for IVF study CS003**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>MENOPUR SC (n = 363)</th>
<th>rFSH SC (n = 368)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ongoing pregnancy</td>
<td>97 (26.7%)</td>
<td>82 (22.3%)</td>
</tr>
<tr>
<td>Clinical pregnancy</td>
<td>100 (27.5%)</td>
<td>87 (23.6%)</td>
</tr>
</tbody>
</table>
A retrospective integrated analysis, comprising 986 IVF patients and 472 ICSI patients in these two trials, has been performed. In patients undergoing IVF, the live birth rate per cycle initiated was 26.5% (130/491) with MENOPUR and 20.8% (103/495) with rFSH (P=0.041). The odds ratio in favour of MENOPUR was 1.36 (95% CI: 1.01-1.83). Results for patients undergoing ICSI showed no statistically significant difference in live birth rate between MENOPUR and rFSH.

INDICATIONS
MENOPUR is indicated for the treatment of infertility in the following clinical situations:

Anovulatory infertility, including polycystic ovarian disease (PCOD), in women who have been unresponsive to treatment with clomiphene citrate.

Controlled ovarian hyperstimulation to induce the development of multiple follicles for assisted reproductive technologies (ART) (e.g. in vitro fertilisation/embryo transfer (IVF/ET), gamete intra-fallopian transfer (GIFT) and intracytoplasmic sperm injection (ICSI)).

CONTRAINDICATIONS
Pregnancy and lactation.

Hypersensitivity to the active substance or any of the excipients used in the formulation.

MENOPUR is contraindicated in women who have:
- Tumours of the pituitary gland or hypothalamus
- Ovarian, uterine or mammary carcinoma
- Gynaecological haemorrhage of unknown aetiology
- Ovarian cysts or enlarged ovaries not due to polycystic ovarian disease.

In the following situations treatment outcome is unlikely to be favourable, and therefore MENOPUR should not be administered:
- Primary ovarian failure
- Malformation of sexual organs incompatible with pregnancy
- Fibroid tumours of the uterus incompatible with pregnancy.

PRECAUTIONS
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.

The luteinising hormone activity of MENOPUR is almost totally contributed by Human Chorionic Gonadotrophin (hCG), which has a longer plasma half-life than Luteinising Hormone. As a consequence, the duration of luteinising hormone activity of MENOPUR may differ from that of recombinant products.
MENOPUR is a potent gonadotrophic substance capable of causing mild to severe adverse reactions, and should only be used by physicians who are thoroughly familiar with infertility problems and their management.

Gonadotrophin therapy requires a certain time commitment by physicians and supportive health professionals, and calls for monitoring of ovarian response with ultrasound, alone or in combination with measurement of serum oestradiol levels, on a regular basis. There is considerable inter-patient variability in response to menotrophin administration, with a poor response to menotrophin in some patients. The lowest effective dose in relation to the treatment objective should be used.

The first injection of MENOPUR should be performed under direct medical supervision.

Before starting treatment, the couple's infertility should be assessed as appropriate and putative contraindications for pregnancy evaluated. In particular, patients should be evaluated for hypothyroidism, adrenocortical deficiency, hyperprolactinaemia and pituitary or hypothalamic tumours, and appropriate specific treatment given.

Patients undergoing stimulation of follicular growth, whether in the frame of a treatment for anovulatory infertility or ART procedures may experience ovarian enlargement or develop hyperstimulation. Adherence to recommended MENOPUR dosage and administration regimen, and careful monitoring of therapy will minimise the incidence of such events. Acute interpretation of the indices of follicle development and maturation requires a physician who is experienced in the interpretation of the relevant tests.

**Ovarian Hyperstimulation Syndrome (OHSS)**

OHSS is a medical event distinct from uncomplicated ovarian enlargement. OHSS is a syndrome that can manifest itself with increasing degrees of severity. It comprises marked ovarian enlargement, high serum sex steroids, and an increase in vascular permeability which can result in an accumulation of fluid in the peritoneal, pleural and, rarely, in the pericardial cavities.

The following symptoms may be observed in severe cases of OHSS: abdominal pain, abdominal distension, severe ovarian enlargement, weight gain, dyspnoea, oliguria and gastrointestinal symptoms including nausea, vomiting and diarrhoea. Clinical evaluation may reveal hypovolaemia, haemoconcentration, electrolyte imbalances, ascites, haemoperitoneum, pleural effusions, hydrothorax, acute pulmonary distress, and thromboembolic events.

Excessive ovarian response to gonadotrophin treatment seldom gives rise to OHSS unless hCG is administered to trigger ovulation. Therefore in cases of ovarian hyperstimulation it is prudent to withhold hCG and advise the patient to refrain from coitus or to use barrier methods for at least 4 days. OHSS may progress rapidly (within 24 hours to several days) to become a serious medical event, therefore patients should be followed for at least two weeks after the hCG administration.

Adherence to recommended MENOPUR dosage, regimen of administration and careful monitoring of therapy will minimise the incidence of ovarian hyperstimulation
and multiple pregnancy. In ART, aspiration of all follicles prior to ovulation may reduce the occurrence of hyperstimulation.

OHSS may be more severe and more protracted if pregnancy occurs. Most often, OHSS occurs after hormonal treatment has been discontinued and reaches its maximum severity at about seven to ten days following treatment. Usually, OHSS resolves spontaneously with the onset of menses.

If severe OHSS occurs, gonadotrophin treatment should be stopped if still ongoing, the patient hospitalised and specific therapy for OHSS started.

Women with polycystic ovarian syndrome (PCOS) are at higher risk of developing OHSS. Other reported risk factors that increase the risk of developing OHSS include previous episodes of OHSS, many follicles and high level of oestradiol.

Systemic diseases
Menotrophin is anticipated to be used in patients who, apart from infertility, are otherwise healthy. The safety of menotrophin in individuals with systemic disease, including renal or hepatic disease, has not been studied and the safety profile in these individuals is unknown. Caution should be used when prescribing menotrophin to individuals with clinically relevant systemic disease.

Multiple pregnancy
Multiple pregnancy, especially high order, carries an increased risk of adverse maternal and perinatal outcomes.

In patients undergoing ovulation induction with gonadotrophins, the incidence of multiple pregnancies is increased compared with natural conception. The majority of multiple conceptions are twins. To minimise the risk of multiple pregnancy, careful monitoring of ovarian response is recommended.

In patients undergoing ART procedures, the risk of multiple pregnancy is related mainly to the number of embryos replaced, their quality and the age of the patient.

The patient should be advised of the potential risk of multiple births before starting treatment.

Pregnancy wastage
The incidence of pregnancy wastage by miscarriage or abortion is higher in patients undergoing stimulation of follicular growth for ART procedures than in the normal population.

Ectopic pregnancy
Women with a history of tubal disease are at risk of ectopic pregnancy, whether the pregnancy is obtained by spontaneous conception or with fertility treatment. The prevalence of ectopic pregnancy after IVF has been reported to be 2 to 5%, as compared to 1 to 1.5% in the general population.

Reproductive system neoplasms
There have been reports of ovarian and other reproductive system neoplasms, both benign and malignant, in women who have undergone multiple drug regimens for
infertility treatment. It is not yet established if treatment with gonadotrophins increases the baseline risk of these tumours in infertile women.

**Congenital malformation**
The prevalence of congenital malformations after ART may be slightly higher than after spontaneous conceptions. This is thought to be due to differences in parental characteristics (e.g. maternal age, sperm characteristics) and multiple pregnancies.

**Thromboembolic events**
Women with generally recognised risk factors for thromboembolic events, such as personal or family history, severe obesity (Body Mass Index > 30 kg/m²) or thrombophilia may have an increased risk of venous or arterial thromboembolic events, during or following treatment with gonadotrophins. In these women, the benefits of gonadotrophin administration need to be weighed against the risks. It should be noted however, that pregnancy itself also carries an increased risk of thromboembolic events.

**Use in pregnancy (Category C)**
MENOPUR is contraindicated in women who are pregnant (see CONTRAINDICATIONS). Although no adequate animal studies have been conducted with MENOPUR, based on its pharmacology and reproductive studies conducted with similar products, an increase in embryonic resorptions and post-implantation loss may be expected at clinically relevant doses.

**Use in lactation**
MENOPUR should not be used during lactation (see CONTRAINDICATIONS).

**Paediatric use**
MENOPUR should not be used in children.

**Use in the elderly**
MENOPUR should not be used in the elderly.

**Genotoxicity**
The genotoxic potential of MENOPUR has not been investigated. Gonadotrophins are naturally occurring proteins and unlikely to pose a genotoxic risk.

**Carcinogenicity**
No carcinogenicity studies have been performed in animals.

**INTERACTIONS WITH OTHER MEDICINES**
No drug/drug interaction studies have been conducted with MENOPUR in humans. Although there is no controlled clinical experience, it is expected that the concomitant use of MENOPUR and clomiphene citrate may enhance the follicular response. When using GnRH agonists for pituitary desensitisation, a higher dose of MENOPUR may be necessary to achieve adequate follicular response.
ADVERSE EFFECTS
Clinical Trials
The most frequently reported adverse drug reactions reported during treatment with MENOPUR in clinical trials are abdominal pain, headache, injection site reactions and injection site pain, with an incidence rate up to 10%. Table 4 displays the main adverse drug reactions in women treated with MENOPUR in clinical trials, distributed by system organ classes (SOCs) and frequency.

Table 4: Adverse Reactions – Clinical Trials

<table>
<thead>
<tr>
<th>System Organ Class</th>
<th>Common (≥1/100 and &lt;1/10)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nervous system disorders</td>
<td>Headache</td>
</tr>
<tr>
<td>Gastrointestinal disorders</td>
<td>Abdominal pain, Nausea, Enlarged abdomen</td>
</tr>
<tr>
<td>Reproductive system disorders</td>
<td>OHSS, Pelvic pain</td>
</tr>
<tr>
<td>General disorders and administration site conditions</td>
<td>Injection site reaction, Injection site pain</td>
</tr>
</tbody>
</table>

Gastrointestinal symptoms associated with OHSS such as abdominal distension and discomfort, nausea, vomiting and diarrhoea have been reported with MENOPUR in clinical trials. As rare complications of OHSS, venous thromboembolic events and ovarian torsion might occur.

Post-marketing Experience
Table 5 displays adverse drug reactions reported in women treated with MENOPUR in the post-marketing period, distributed by system organ classes (SOCs).

Table 5: Adverse Reactions – Post Marketing

<table>
<thead>
<tr>
<th>System Organ Class</th>
<th>Frequency not known*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immune system disorders</td>
<td>Hypersensitivity**</td>
</tr>
<tr>
<td>Nervous system disorders</td>
<td>Dizziness</td>
</tr>
<tr>
<td>Eye disorders</td>
<td>Visual disorders***</td>
</tr>
<tr>
<td>Skin and subcutaneous tissue disorders</td>
<td>Rash, Pruritus</td>
</tr>
<tr>
<td>Musculo-skeletal and connective tissue disorders</td>
<td>Arthralgia</td>
</tr>
<tr>
<td>Reproductive system disorders</td>
<td>Breast tenderness</td>
</tr>
<tr>
<td>General disorders and administration site conditions</td>
<td>Pyrexia</td>
</tr>
</tbody>
</table>

* The frequency of adverse drug reactions reported during the post-marketing period is regarded as unknown.
** Allergic reactions localised or generalised, including anaphylactic reaction.
*** Vision disorders such as blurred vision, vision impairment including amaurosis, diplopia, mydriasis, photopsia, scotoma and vitreous floaters have been reported with MENOPUR during the post-marketing period.

DOSAGE AND ADMINISTRATION
Treatment with MENOPUR should be initiated under the supervision of a physician experienced in the treatment of fertility problems.

Method of administration
MENOPUR is intended for subcutaneous (S.C.) injection after reconstitution with the solvent provided.
The powder should be reconstituted prior to use. The reconstituted solution is for multiple injections and can be used for up to 28 days. Each reconstituted MENOPUR 600 IU or 1200 IU vial should be for individual patient use only.

**General**
Vigorous shaking should be avoided. The solution should not be used if it contains particles or if it is not clear.

**Dosage**
There are great inter-individual variations in the response of the ovaries to exogenous gonadotrophins. This makes it impossible to set a uniform dosage scheme. The dosage should, therefore, be adjusted individually depending on the ovarian response. MENOPUR can be given alone or in combination with a gonadotrophin-releasing hormone (GnRH) agonist or antagonist. Recommendations about dosage and duration of treatment may change depending on the actual treatment protocol.

**Women with anovulatory infertility (including PCOD)**
The object of MENOPUR therapy is to develop a single Graafian follicle from which the oocyte will be liberated after the administration of human chorionic gonadotrophin (hCG).

MENOPUR therapy should start within the initial 7 days of the menstrual cycle. The recommended initial dose of MENOPUR is 75-150 IU daily, which should be maintained for at least 7 days. Based on clinical monitoring (including ovarian ultrasound alone or in combination with measurement of oestradiol levels) subsequent dosing should be adjusted according to individual patient response. Adjustments in dose should not be made more frequently than every 7 days. The recommended dose increment is 37.5 IU per adjustment, and should not exceed 75 IU. The maximum daily dose should not be higher than 225 IU. If a patient fails to respond adequately after 4 weeks of treatment, that cycle should be abandoned and the patient should recommence treatment at a higher starting dose than in the abandoned cycle.

When an optimal response is obtained, a single injection of 5,000 IU to 10,000 IU hCG should be given 1 day after the last MENOPUR injection. The patient is recommended to have coitus on the day of and the day following hCG administration. Alternatively intrauterine insemination (IUI) may be performed. If an excessive response to MENOPUR is obtained treatment should be stopped and hCG withheld (see PRECAUTIONS) and the patient should use a barrier method of contraception or refrain from having coitus until the next menstrual bleeding has started.

**Women undergoing controlled ovarian hyperstimulation for multiple follicular development for assisted reproductive technologies (ART)**
In line with clinical trials with MENOPUR that involved downregulation with GnRH agonists, MENOPUR therapy should start approximately 2 weeks after the start of agonist treatment. The recommended initial dose of MENOPUR is 150-225 IU daily for at least the first 5 days of treatment. Based on clinical monitoring (including ovarian ultrasound alone or in combination with measurement of oestradiol levels) subsequent dosing should be adjusted according to individual patient response, and should not exceed more than 150 IU per adjustment. The maximum daily dose given should not be higher than 450 IU daily and in most cases dosing beyond 20 days is not recommended.
In protocols not involving downregulation with GnRH agonists, MENOPUR therapy should start on day 2 or 3 of the menstrual cycle. It is recommended to use the dose ranges and regimen of administration suggested above for protocols with downregulation with GnRH agonists.

When a suitable number of follicles have reached an appropriate size, a single injection of up to 10,000 IU hCG should be administered to induce final follicular maturation in preparation for oocyte retrieval. Patients should be followed closely for at least 2 weeks after hCG administration. If an excessive response to MENOPUR is obtained treatment should be stopped and hCG withheld (see PRECAUTIONS) and the patient should use a barrier method of contraception or refrain from having coitus until the next menstrual bleeding has started.

**Instructions for use and handling**
The powder should only be reconstituted with the solvent provided in the package.

Attach the reconstitution needle to the prefilled syringe. Inject the total contents of solvent into the vial containing the powder. MENOPUR 600 IU must be reconstituted with one pre-filled syringe with solvent before use. MENOPUR 1200 IU must be reconstituted with two pre-filled syringes with solvent before use. The powder should dissolve quickly to a clear solution. If not, roll the vial gently between the hands until the solution is clear. Vigorous shaking should be avoided.

The administration syringes are graduated in FSH/LH units from 37.5 - 600 IU and supplied with needles in the MENOPUR multidose box. Draw up the reconstituted solution from the vial into the administration syringe for injection according to the prescribed dose. Each mL of reconstituted solution contains 600 IU FSH and LH.

Draw up the exact dose of reconstituted solution from the vial into the syringe for injection and administer the dose immediately.

**General**
The reconstituted solution should not be administered if it contains particles or is not clear. Any unused product or waste material should be disposed in accordance with local requirements.

**OVERDOSAGE**
The effects of an overdose are unknown, nevertheless one could expect ovarian hyperstimulation syndrome to occur.

**PRESENTATION AND STORAGE CONDITIONS**
MENOPUR is available in the following containers and pack sizes:

**MENOPUR 600 IU**
Powder: 2 mL colourless glass (Type I glass) vial with rubber stopper closed with a cap.
Solvent: 1 mL pre-filled syringe (Type I glass) with rubber tip cap and plunger, rubber stopper.
The product is supplied as a pack of 1 vial of powder, 1 pre-filled syringe with solvent for reconstitution, 1 needle for reconstitution, 9 alcohol pads and 9 disposable syringes for administration graduated in FSH/LH units with pre-fixed needles.

**MENOPUR 1200 IU**

Powder: 2 mL colourless glass (Type I glass) vial with rubber stopper closed with a cap.
Solvent: 1 mL pre-filled syringe (Type I glass) with rubber tip cap and plunger, rubber stopper.

The product is supplied as a pack of 1 vial of powder, 2 pre-filled syringes with solvent for reconstitution, 1 needle for reconstitution, 18 alcohol pads and 18 disposable syringes for administration graduated in FSH/LH units with pre-fixed needles.

**Storage conditions**

Store in a refrigerator (2°C to 8°C). Do not freeze. Store in the original container. To reduce microbiological hazard, the reconstituted solution should be stored in a refrigerator and must be discarded after 28 days. Chemical and in-use stability have been demonstrated for reconstituted product stored for up to 28 days at not more than 25°C.

**NAME AND ADDRESS OF THE SPONSOR**

Ferring Pharmaceuticals Pty Ltd  
Suite 2, Level 1, Building 1, 20 Bridge Street  
Pymble NSW 2073

**POISON SCHEDULE OF THE MEDICINE**

Prescription Medicine

**Date of first inclusion in the Australian Register of Therapeutic Goods (ARTG)**

13 September 2011

**Date of most recent amendment**

N/A