SCHEDULING STATUS

S4 / S4

1. NAME OF THE MEDICINE

MENOPUR ® 75 IU, Powder for solution for injection

MENOPUR ® SOLVENT, Solution for injection

MENOPUR ® 600 IU, Powder and solvent for solution for injection

MENOPUR ® 1200 IU, Powder and solvent for solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

MENOPUR ® 75 IU: Each vial with powder contains highly purified menotrophin (human menopausal gonadotrophin, hMG) corresponding to follicle stimulating hormone activity (FSH) 75 IU and luteinising hormone activity (LH) 75 IU.

Powder contains sugar (lactose monohydrate, 20 mg/vial).

MENOPUR ® 600 IU: 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.

Powder contains sugar (lactose monohydrate, 21 mg/vial).

Solvent contains metacresol (0,33 % *m/v*) as preservative.

MENOPUR ® 1200 IU: 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.

Powder contains sugar (lactose monohydrate, 21 mg/vial).

Solvent contains metacresol (0,33 % *m/v*) as preservative.

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

MENOPUR ® 75 IU: Powder for solution for injection.

MENOPUR ® SOLVENT: Solution for injection.

MENOPUR ® 600 IU: Powder and solvent for solution for injection.

MENOPUR ® 1200 IU: Powder and solvent for solution for injection.

MENOPUR ® 75 IU: Powder for solution for injection is a white to off-white lyophilised cake.

MENOPUR ® SOLVENT: Solution for injection is a clear colourless solution.

The reconstituted solution is a clear colourless solution free from any foreign particles.

MENOPUR ® 600 IU:

Powder: white to off-white lyophilisation cake.

Solvent: clear colourless solution, free from any foreign particles.

MENOPUR ® 1200 IU:

Powder: white to off-white lyophilisation cake.

Solvent: clear colourless solution, free from any foreign particles.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Female:

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

WHO group II anovulation 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).

Male:

MENOPUR ® has been used for oligospermia, some types of azoospermia, hypogonadism, eunuchoidism.

4.2 Posology and method of administration

Treatment with MENOPUR ® should be initiated under the supervision of a medical practitioner experienced in the treatment of fertility problems.

Posology

MENOPUR ® 75 IU: Dosage regimens described below are identical for subcutaneous (S.C.) and intramuscular (I.M). administration.

MENOPUR ® 600 IU and MENOPUR ® 1200 IU: For subcutaneous use only (see 'Method of administration')

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 (sonographic visualisation of a follicle ≥ 10 mm). 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 anovulation (including PCOD):

The objective 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 to 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. Adjustment in dose should not be made more frequently than every 7 days. The recommended dose increment is 37,5 IU per dose 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 intra-uterine insemination (IUI) may be performed. If an excessive response to MENOPUR ® is obtained treatment should be stopped and hCG withheld (see section 4.4) 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 dosing beyond 20 days is not recommended.

In a protocol using down-regulation with a GnRH antagonist, 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 administrated 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 section 4.4) and the patient should use a barrier method of contraception or refrain from having coitus until the next menstrual bleeding has started.

Dosage for men:

The recommended treatment consists of 75 IU of MENOPUR ® every other day for at least 90 to 120 days. Should semen volume remain lower than 1,5 mL, it is advisable to add 2500 IU of hCG once or twice weekly, particularly towards the end of treatment.

Maintenance treatment should be 75 IU to 150 IU of MENOPUR ® every week. Prior to starting treatment, an assay of urinary gonadotrophins will be useful for discharging those cases which present above average results.

In cases of oligospermia, a complete semen examination is sufficient, whereas for azoospermia cases, testicular biopsy is quite useful in order to eliminate from treatment those patients, most of whose seminiferous tubules contain only Sertoli’s cells, which do not seem to respond favourably.

Special populations

Elderly

There is no relevant use of MENOPUR ® in the elderly population.

Paediatric population

There is no relevant use of MENOPUR ® in the paediatric population.

Method of administration

MENOPUR ® 75 IU is intended for S.C. or I.M. injection after reconstitution with the solvent provided.

The powder should be reconstituted prior to use (see section 6.6). In order to avoid the injection of large volumes up to 3 vials of the powder may be dissolved in 1 mL of the solvent provided.

Shaking should be avoided. The solution should not be used if it contains particles or if it not clear.

MENOPUR ® 600 IU and 1200 IU are intended for S.C. injection, as the syringe provided is for S.C. administration only.

The powder should be reconstituted prior to use (see section 6.6). The reconstituted solution is for multiple injections and can be used for up to 28 days.

Shaking should be avoided.

The solution should not be used if it contains particles or if it is not clear

For instructions on reconstitution and other handling, see section 6.6.

4.3 Contraindications

- Hypersensitivity to the active substance, menotrophin, or to any of the excipients listed in section 6.1.

- Pregnancy and lactation.
- Tumours in the uterus, ovaries, breasts, testes, prostate, pituitary gland or hypothalamus.
- Gynaecological bleeding of unknown origin.
- Patients presenting with polycystic ovaries, or who are capable of ovulating with human chorionic gonadotrophic (hCG) administration alone.
- Ovarian cysts or enlarged ovaries not due to polycystic ovarian disease.
- Primary ovarian failure.
- Malformation of sexual organs incompatible with pregnancy.
- Fibroid tumours of the uterus incompatible with pregnancy.

4.4 Special warnings and precautions for use

MENOPUR ® should only be used by medical practitioners who are thoroughly familiar with infertility problems and their management.

MENOPUR ® requires a certain time commitment by medical practitioners 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 MENOPUR ® administration, with a poor response to MENOPUR ® 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 lesions, 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 regimen of administration and careful monitoring of therapy will minimise the incidence of such events. Acute interpretation of the indices of follicle development and maturation requires a medical practitioner 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 of 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, less frequently, in the pericardial cavities.

Patients who have ovarian enlargement are at risk of rupture. Pelvic examinations should be avoided or carried out with care.

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.

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 (see section 4.2). 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.
This syndrome occurs with higher incidence in patients with polycystic ovarian 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 medicine regimens for infertility treatment. It is not yet established if treatment with gonadotrophins, including MENOPUR ®, 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/m^2) or thrombophilia may have an increased risk of venous or arterial thromboembolic events, during or following treatment with MENOPUR ®.

In these women, the benefits of MENOPUR ® administration need to be weighed against the risks.

Excipients

MENOPUR ® contains less than 1 mmol sodium (23 mg) per vial, that is to say essentially ‘sodium-free’.

4.5 Interaction with other medicines and other forms of interaction

No 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 agonist for pituitary desensitisation, a higher dose of MENOPUR ® may be necessary to achieve adequate follicular response.

In women who show evidence of excessive ovarian stimulation while receiving MENOPUR ®, the administration of medicines with luteinising hormone (LH) activity increases the risk of ovarian hyperstimulation syndrome.

4.6 Fertility, pregnancy and lactation

Pregnancy

MENOPUR ® is contraindicated in women who are pregnant (see section 4.3).

Breastfeeding

MENOPUR ® is contraindicated in women who are breastfeeding (see section 4.3).

Fertility

MENOPUR ® is indicated for use in infertility (see section 4.1).

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed. However, MENOPUR ® may cause dizziness and this may affect the patient's ability to drive and use machines.

4.8 Undesirable effects

a. Summary of the safety profile

The most frequently reported adverse drug reactions (ADR) during treatment with MENOPUR ® in clinical trials are Ovarian Hyperstimulation Syndrome (OHSS), headache, abdominal pain, abdominal distension and injection site pain.

Men:

With regard to the gonadotrophin treatment, gynaecomastia, acne and weight gain have been reported. Additionally, administration site reactions and hypersensitivity could also be expected in the male population.

b. Tabulated list of adverse reactions

The table below displays the main ADRs in women treated with MENOPUR ® in clinical trials distributed by system organ classes (SOCs) and frequency. Further, the ADRs seen during post marketing experience are mentioned with unknown frequency.

Side effects are classified according to the following frequency classes:

System Organ class	**Common** ***≥ 1/100 to < 1/10***	**Uncommon** ***≥ 1/1 000 to < 1/100***	**Rare** ***≥ 1/10 000 to < 1/1 000***	**[1]Unknown**
Eye disorders				Visual disorders [a]
Gastro-intestinal disorders	Abdominal pain, Abdominal distension, Nausea	Vomiting, Abdominal discomfort, Diarrhoea		
General disorders	Injection site	Fatigue		Pyrexia, Malaise

and administration site conditions	reactions			
Immune system disorders				Hyper-sensitivity reactions [b]
Investigations				Weight increased
Musculo-skeletal & connective tissue disorders				Musculo-skeletal pain [c]
Nervous system disorders	Headache	Dizziness		
Reproductive system and breast disorders	Ovarian hyperstimulation syndrome (OHSS) [d], pelvic pain	Ovarian cyst, Breast complaints		Ovarian torsion [d]
Skin and subcutaneous tissue disorders			Acne, Rash	Pruritus, Urticaria
Vascular disorders		Hot flush		Thrombo-embolism [d]

c. Description of selected adverse reactions

[1] The ADRs seen during post-marketing experience are listed with unknown frequency.

[a] Individual cases of temporary amaurosis, diplopia, mydriasis, scotoma, photopsia, vitreous floaters, vision blurred and vision impairment have been reported.

[b] Cases of localised or generalised allergic reactions, including anaphylactic reaction, along with

associated symptomatology have been reported.

[c] Musculoskeletal pain includes arthralgia, back pain, neck pain and pain in extremities.

[d] In cases of severe OHSS, ascites and pelvic fluid collection, pleural effusion, dyspnoea, oliguria, thromboembolic events and ovarian torsion have been reported.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/documents/adverse-drug-reactions-and-quality-problem-reporting-form.

4.9 Overdose

The effect of an overdose is unknown, nevertheless one could expect ovarian hyperstimulation syndrome (OHSS) to occur (see section 4.4).

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Class of medicine: A 21.10 Trophic Hormones

A 34.13 Other

ATC code: G03G A02

Menotrophin possesses both follicle-stimulating hormone (FSH) activity and luteinising hormone (LH) activity.

Menotrophin induces ovarian follicular growth and development as well as gonadal steroid production in women who do not have primary ovarian failure.

In males FSH stimulates spermatogenic function and LH stimulates the Leydig cell and steroidogenesis.

5.2 Pharmacokinetic properties

Distribution

After 7 days of repeated dosing with 150 IU MENOPUR ® in down regulated healthy female volunteers, maximum plasma FSH concentrations (baseline-corrected) (mean ± SD) were 8,9 ± 3,5 IU/L and 8,5 ± 3,2 IU/L for the SC and IM administration, respectively. Maximum FSH concentrations were reached within 7 hours for both routes of administration.

Elimination

After repeated administration, FSH was eliminated with a half-life (mean ± SD) of 30 ± 11 hours and 27 ± 9 hours for the SC and IM administration, respectively. Although the individual LH concentration versus time curves shows an increase in the LH concentration after dosing with MENOPUR ®, the data available were too sparse to be subjected to a pharmacokinetic analysis.

Menotrophin is excreted primarily via the kidneys. The pharmacokinetics of MENOPUR ® in patients with renal or hepatic impairment has not been investigated.

Menotrophin is eliminated predominantly by urinary excretion, of which 8 % is excreted unchanged.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

MENOPUR ® 75 IU:

Powder

Lactose monohydrate

Polysorbate 20

Sodium hydroxide (for pH adjustment)

Hydrochloric acid (for pH adjustment)

MENOPUR ® SOLVENT:

Sodium chloride (for adjustment of osmolality)

Diluted hydrochloric acid (10 % *w/w*) (for pH adjustment)

Water for injection

MENOPUR ® 600 IU and MENOPUR ® 1200 IU:

Powder

Lactose monohydrate

Polysorbate 20

Sodium phosphate dibasic heptahydrate (for buffer and pH adjustment)

Phosphoric acid (concentrated) (for pH adjustment)

Solvent

Metacresol (m-cresol)

Water for injection

6.2 Incompatibilities

In the absence of compatibility studies, MENOPUR ® must not be mixed with other medicines.

6.3 Shelf life

MENOPUR ® 75 IU:

24 months when stored not above 30 ºC.

MENOPUR ® SOLVENT:

36 months when stored not above 30 ºC.

MENOPUR ® 600 IU and 1200 IU:

Powder: 36 months when stored at 2 °C to 8 °C.

Solvent: 36 months when stored at 2 °C to 8 °C.

Reconstituted: 28 days when stored not above 30 °C.

6.4 Special precautions for storage

MENOPUR ® 75 IU and MENOPUR ® SOLVENT:

Do not store above 30 ºC. Do not freeze.

Store in the original container in order to protect from light.

For immediate and single use following reconstitution.

Discard any unused portion.

MENOPUR ® 600 IU and 1200 IU:

Prior to reconstitution: Store in refrigerator (2 °C to 8 °C). Do not freeze.

Store in the original container, within the outer carton until required for use.

After reconstitution: The solution can be stored for up to 28 days below 30 ºC. Do not freeze.

6.5 Nature and contents of container

MENOPUR ® 75 IU: 2 R (2 mL) x 1 colourless glass (Type 1) vials with rubber stopper closed with a cap.

MENOPUR ® SOLVENT: 1 mL colourless glass (Type 1) ampoule.

MENOPUR ® 75 IU is supplied in packs of 10 vials with the corresponding number of MENOPUR ® SOLVENT ampoules.

MENOPUR ® 600 IU:

Powder: 2 mL colourless glass (type 1 glass) vial with a rubber stopper closed with a cap.

Solvent: 1 mL pre-filled syringe (type 1 glass) with rubber tip cap and plunger rubber stopper.

MENOPUR ® 600 IU is supplied as a pack of 1 vial of powder, 1 pre-filled syringe with solvent for reconstitution, 1 needle for reconstitution and 9 disposable syringes for administration graduated in FSH/LH units with prefixed needles.

MENOPUR ® 1200 IU:

Powder: 2 mL colourless glass (type 1 glass) vial with a rubber stopper closed with a cap.

Solvent: 1 mL pre-filled syringe (type 1 glass) with rubber tip cap and plunger rubber stopper

MENOPUR ® 1200 IU is supplied as a pack of 1 vial of powder, 2 pre-filled syringes with solvent for reconstitution, 1 needle for reconstitution and 18 disposable syringes for administration graduated in FSH/LH units with prefixed needles.

6.6 Special precautions for disposal and or other handling

The powder should only be reconstituted with the solvent provided.

The solution should not be used if it contains particles or if it is not clear.

MENOPUR ® 75 IU:

Attach the reconstitution needle to the syringe. Withdraw the entire content from the ampoule with solvent and inject

the total contents into the vial containing the powder. The powder should dissolve quickly to a clear solution. If not, roll the vial gently between the hands until the solution is clear. Shaking should be avoided.

In order to avoid the injection of large volumes up to 3 vials of the powder may be dissolved in 1 mL of the solvent provided.

When the prescribed dose has been reached, draw up the mixed solution from the vial into the syringe, change to the hypodermic needle and administer immediately.

MENOPUR ® 600 IU and 1200 IU:

Attach the reconstitution needle to the prefilled syringe. Inject the total contents of solvent into the vial containing the powder. The powder should dissolve quickly to a clear solution. If not, roll the vial gently between the hands until the solution is clear. Shaking should be avoided.

Please note:

Make sure to use one (1) pre-filled syringe of the solvent for MENOPUR ® 600 IU and two (2) pre-filled syringes of the solvent for MENOPUR ® 1200 IU.

The single use administration syringes are graduated in FSH/LH units from

37, 5 to 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 and administer the dose immediately. Each mL of reconstituted solution contains 600 IU FSH and LH.

Each reconstituted MENOPUR ® 600 IU or 1200 IU vial should be for individual patient use only.

Any unused product or waste material should be disposed of, in accordance with local requirements for pharmaceutical waste disposal.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Ferring (Pty) Ltd.

Route 21 Corporate Park

6 Regency Drive

Irene Ext. 30

Pretoria, Gauteng, 0157

South Africa

8. REGISTRATION NUMBER

MENOPUR ® 75 IU: A39/21.10/0357

MENOPUR ® SOLVENT: A39/34/0412

MENOPUR ® 600 IU: A44/21.10/0382

MENOPUR ® 1200 IU: A44/21.10/0383

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of registration:

6 October 2006 (MENOPUR ® 75 IU & MENOPUR ® SOLVENT) & 20 March 2018 (MENOPUR ® 600 IU & MENOPUR ® 1200 IU)

10. DATE OF REVISION OF THE TEXT

12 May 2025

NAME AND BUSINESS ADDRESS OF THE MANUFACTURER

Ferring GmbH

Wittland 11, D-24109 Kiel,

Germany

Namibia

NS2	MENOPUR ® 75 IU Powder and solvent for solution for injection	07/21.10/0085
NS2	MENOPUR ® 600 IU Powder for solution for injection	18/21.10/0118
NS2	MENOPUR ® 1200 IU Powder for solution for injection	18/21.10/0119
NS2	MENOPUR ® 600 IU & 1200 IU Solvent for solution for injection:	18/34/0128