Prescribing information for Meriofert (Menotrophin) 75 IU AND 150 IU Powder and solvent for solution for injection (Refer to Summary of Product Characteristics (SPC) for full information).

Presentation: Meriofert 75 IU - Each freeze-dried vial contains 75 IU human follicle stimulating hormone activity (FSH) and 75 IU human luteinising hormone activity (LH). Meriofert 150IU – Each freeze-dried vial contains 150 IU human follicle stimulating hormone activity (FSH) and 150 IU human luteinising hormone activity (LH). Powder: white to almost white lyophilized powder. Solvent: clear and colourless solution.

Indications: Ovulation induction. Controlled ovarian hyperstimulation (COH) within a medically assisted reproduction technology (ART): induction of multiple follicular development in women undergoing assisted reproduction techniques such as in vitro fertilization (IVF). The product is not intended for paediatric use.

Dosage and administration: Intended for subcutaneous and intramuscular administration. The powder should be reconstituted immediately prior to use with the solvent provided. In order to avoid injection of large volumes up to 6 vials may be dissolved in 1 ml of solvent. Treatment should be adjusted to the individual patient's response as assessed by measuring follicular development by ultrasound and/or measurement of oestrogen levels. A commonly used regimen for ovulation induction in females with anovulation starts at 75 to 150 IU of FSH per day and is increased if necessary by 37.5 IU (up to 75 IU), with intervals of 7 or 14 days preferably, in order to achieve an adequate but not excessive response. A commonly used protocol for ovary stimulation commences at 150-225IU of Meriofert daily for the first five to seven days, the dose is adjusted according to the patient's response but the maximum daily dose is usually not higher than 450 IU. (See SPC for full details).

Contra-indications: Hypersensitivity to Menotrophin or to any of the excipients. Ovarian enlargement or cysts not related to polycystic ovarian syndrome. Gynaecological bleeding of unknown cause. Ovarian, uterine or breast carcinoma. Tumours of the hypothalamus or pituitary gland. Meriofert is contraindicated when an effective response cannot be achieved, for example: Primary ovarian failure. Malformations of sexual organs incompatible with pregnancy. Fibroid tumours of the uterus incompatible with pregnancy.

Warnings and precautions: Anaphylactic reactions may occur, particularly in patients with known hypersensitivity to gonadotropins. The first injection of Meriofert should always be performed under direct medical supervision and in settings with facilities for cardio-pulmonary resuscitation. Ultrasonographic assessment of follicular development, and determination of oestradiol levels should be performed prior to treatment and monitored at regular intervals during treatment. This is particularly important at the beginning of the stimulation in order to avoid Ovarian Hyperstimulation Syndrome. The diagnosis of ovarian hyperstimulation may be confirmed by ultrasound examination. If this unwanted ovarian hyperstimulation occurs (i.e. not as part of controlled ovarian hyperstimulation in medically assisted reproduction programs), the administration of Meriofert should be discontinued. (See SPC for full details).

Interactions: Although there is no clinical experience, it is expected that the concomitant use of Meriofert 75-150 IU and clomiphene citrate may enhance the follicular response. When using GnRH agonist for pituitary desensitisation, a higher dose of Meriofert 75-150 IU may be necessary to achieve adequate follicular response.

Pregnancy and Lactation: Meriofert is contraindicated.

Undesirable Effects: The most frequent adverse reactions with Meriofert were headache and abdominal distension as well as nausea, fatigue, dizziness and pain at the injection site. The most relevant occurring adverse drug reaction in clinical trials with Meriofert is (dose-related) ovarian

hyperstimulation (OHSS), generally mild with small ovarian enlargement, abdominal discomfort or pain. Only one case of OHSS was serious. (See SPC for full details).

Pack size and NHS List Price: 10 vials of Meriofert 75 IU and 10 ampoules of solvent (1 ml) - £279.00, 10 vials of Meriofert 150 IU and 10 ampoules of solvent (1 ml) - £558.00.

Marketing Authorisation Numbers: Meriofert 75 IU - PL 21039/0046 and Meriofert 150 IU – PL 21039/0047.

Legal Classification: POM

Marketing Authorisation Holder: IBSA Farmaceutici Italia S.r.l, Via Martiri di Cefalonia 2, 26900 Lodi, Italy.

Date of last revision of PI text: March 2023.

Approval code: UKME00112