Prescribing Information: Rekovelle® (follitropin delta) recombinant human follicle-stimulating hormone (FSH) pre-filled multidose pen (12 micrograms/0.36 ml, 36 micrograms/1.08 ml and 72 micrograms/2.16 ml) solution for injection.

Please consult the full Summary of Product Characteristics before prescribing. Name of Product: Rekovelle solution for injection available in pre-filled multidose pens containing 12, 36 and 72 micrograms (mcg) follitropin delta. 1ml of solution contains 33.3mcg of follitropin delta (FSH produced in a human cell line (PER.C6) by recombinant DNA technology). **Composition: Rekovelle 12mcg/0.36ml.** One pre-filled pen contains 12mcg follitropin delta in 0.36ml solution. **Rekovelle 36mcg/1.08ml.** One pre-filled pen contains 36mcg follitropin delta in 1.08ml solution. **Rekovelle 72 mcg/2.16ml.** One pre-filled pen contains 72mcg follitropin delta in 2.16ml solution. **Indications:** Controlled ovarian stimulation for the development of multiple follicles in women undergoing assisted reproductive technologies such as an in vitro fertilisation or intracytoplasmic sperm injection cycle. **Dosage and administration:** Rekovelle is dosed in mcg and is individualised for each patient. Intended for subcutaneous use, preferably in abdominal wall. For the first treatment cycle, the daily dose is determined on the basis of the woman's body weight and serum anti-Müllerian hormone (AMH) concentration based on a recent determination of AMH (i.e. within the last 12 months) measured by one of the following immunoassay tests: Roche ELECSYS AMH Plus, the Beckman Coulter ACCESS AMH Advanced, or Fujirebio LUMIPULSE G AMH. The individual daily dose is maintained throughout the stimulation period. For women with AMH <15 pmol/L the daily dose is 12mcg, irrespective of body weight. For women with AMH ≥15 pmol/L the daily dose decreases from 0.19 to 0.10mcg/kg by increasing AMH concentration. The maximum daily dose for the first treatment cycle is 12mcg. Potential high responders (AMH >35 pmol/L) have not been studied using down-regulation with GnRH agonist. Timing of initiating Rekovelle depends on protocol type: if using GnRH antagonist, initiate treatment on day 2 or 3 after start of menstrual bleeding. If using down-regulation with a GnRH agonist, initiate Rekovelle approximately 2 weeks after starting agonist treatment. Continue until adequate follicular development has been achieved, which is on average by ninth or tenth treatment day (range 5-20 days). With pituitary desensitization caused by a GnRH agonist, a longer duration of stimulation and higher total dose of Rekovelle may be necessary to achieve adequate follicular response. Administer a single injection of 250mcg recombinant human chorionic gonadotropin (hCG) or 5,000 IU hCG to induce final follicular maturation. If excessive follicular development (≥25 follicles ≥12mm), Rekovelle® should be stopped and triggering of final follicular maturation with hCG should not be performed. For subsequent treatment cycles, the daily dose of Rekovelle should be maintained or modified according to the patient's ovarian response in the previous cycle. If the patient had adequate ovarian response in the previous cycle without developing OHSS, use the same daily dose. In case of ovarian hypo-response in the previous cycle, the daily dose in the subsequent cycle should be increased by 25% or 50%, according to the extent of response observed. In case of ovarian hyper-response in the previous cycle, the daily dose in the subsequent cycle should be decreased by 20% or 33%, according to the extent of response observed. In patients who developed OHSS or were at risk of OHSS in a previous cycle, the daily dose for the subsequent cycle is 33% lower than the dose used in the cycle where OHSS or risk of OHSS occurred. The maximum daily dose is 24mcg. **Contraindications:** Tumours of the hypothalamus or pituitary gland; ovarian enlargement or ovarian cyst not due to polycystic ovarian syndrome; gynaecological haemorrhages of unknown aetiology; ovarian, uterine or mammary carcinoma; hypersensitivity to the active substance or to any of the excipients. Do not administer in primary ovarian failure, malformations of sexual organs incompatible with pregnancy, fibroid tumours of the uterus incompatible with pregnancy. **Special Warnings and Precautions:** Should only be used by physicians thoroughly familiar with infertility management. Before treatment initiation, evaluate patients for hypothyroidism and hyperprolactinaemia and treat appropriately. The first injection of Rekovelle should be performed under direct medical supervision. Use of results obtained with assays other than those listed above for Rekovelle dose determination is not recommended, as there is currently no standardisation of available AMH assays. Patients undergoing stimulation of follicular growth may experience ovarian enlargement and may be at risk of developing OHSS. Rekovelle has not been studied in patients with moderate/severe renal or hepatic impairment. *OHSS*: Monitor follicular development carefully and frequently to reduce risk of OHSS. In cases of ovarian hyperstimulation, withhold hCG and advise patients to refrain from coitus or use barrier contraceptive methods for at least 4 days. Due to risk of developing OHSS, patients should be followed for at least 2 weeks after triggering of final follicular maturation. *Thromboembolic events*: Women with recent or ongoing thromboembolic disease or with recognised risk factors may have an increased risk of venous or arterial thromboembolic events during or following treatment with gonadotropins. Weigh benefit against risk. *Ovarian torsion*: Has been reported for ART cycles. *Multiple pregnancy*: Advise patients of potential risk of multiple births before starting treatment. *Pregnancy loss*: Incidence of pregnancy loss by miscarriage or abortion is higher in patients undergoing controlled ovarian stimulation for ART than following natural conception. *Ectopic pregnancy*: Prevalence after ART has been reported to be higher than in general population. *Reproductive system neoplasms*: It is not established whether or not treatment with gonadotropins increases the risk of these tumours in infertile women. *Congenital malformation*: Prevalence may be slightly higher after ART than after spontaneous conceptions. **Interactions:** Clinically significant interactions with other medicines are not expected. **Pregnancy/breastfeeding:** Not indicated during pregnancy or breastfeeding. **Side effects:** *Common:* Headache, nausea, OHSS, pelvic pain, adnexa uterine pain, pelvic discomfort, fatigue. *Uncommon:* Mood swings, somnolence, dizziness, diarrhoea, vomiting, constipation, abdominal discomfort, vaginal haemorrhage, breast discomfort. breast pain, breast tenderness. **Marketing Authorisation Number:** PLGB 03194/0133 (12mcg), 03194/0134 (36mcg), 03194/0135 (72mcg). **Marketing Authorisation Holder:** Ferring Pharmaceuticals Ltd, Drayton Hall, Church Road, West Drayton, UB7 7PS. **Legal category:** POM. **Basic NHS price:** Rekovelle 12 mcg/0.36ml £118.31; Rekovelle 36mcg/1.08ml £354.94; Rekovelle 72mcg/2.16ml £709.89 **Date of preparation:** February 2025. Rekovelle is a registered trademark. **PI Job Code: UK-REK-2500003**

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**