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 containing12, 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. There is no clinical trial experience with Rekovelle in the long GnRH agonist protocol. **Dosage and administration:** Rekovelle is dosed in mcg and is individualised for each patient. 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 to be 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. Treatment should be initiated day 2 or 3 after start of menstrual bleeding and should be continued until adequate follicular development has been achieved followed by 250mcg recombinant human chorionic gonadotropin (hCG) or 5,000 IU hCG. 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, the same daily dose should be used. 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. 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. **Special Warnings and Precautions:** Should only be used by physicians thoroughly familiar with infertility management. 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. **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 pain, breast tenderness. **Storage:** store in a refrigerator (2°C-8°C). Do not freeze. Store in the original package in order to protect from light. **Presentation: Rekovelle 12mcg/0.36 ml**: 3ml multidose cartridge; each cartridge contains 0.36ml of solution. Pack size of 1 pre-filled pen with injection needles. **Rekovelle 36 mcg/1.08 ml:** 3 ml multidose cartridge; each cartridge contains 1.08 ml of solution. Pack size of 1 pre-filled pen with injection needles. **Rekovelle 72mcg/2.16 ml:** 3ml multidose cartridge; each cartridge contains 2.16ml of solution. Pack size of 1 pre-filled pen with injection needles. **Marketing Authorisation Number:** EU/1/16/1150/004–12mcg; EU/1/16/1150/005–36mcg; EU/1/16/1150/006–72mcg. **Marketing Authorisation Holder:** Ferring Pharmaceuticals A/S, Kay Fiskers Plads 11, 2300 Copenhagen S, Denmark. **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:** December 2021. Rekovelle is a registered trademark. **PI Job Code UK-REK-2100002**

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**