Prescribing Information: Lutigest® (progesterone) 100mg vaginal tablets.

Please consult the full Summary of Product Characteristics before prescribing.

Name of Product: Lutigest® 100mg vaginal tablets.

Composition: Each vaginal tablet contains 100mg progesterone.

Indication: Lutigest® is indicated for luteal support as part of an Assisted Reproductive Technology (ART) treatment program for infertile women.
Dosage and administration: The dose of Lutigest® is 100mg administered vaginally three times daily starting at oocyte retrieval. Lutigest® is to be placed directly into the vagina by the applicator provided. The administration of Lutigest® should be continued for 30 days if pregnancy has been confirmed.
Contraindications: Lutigest® should not be used in individuals with the following conditions: hypersensitivity to the active substance or any of the other excipients; undiagnosed vaginal bleeding; known missed abortions or ectopic pregnancy; severe hepatic dysfunction or disease; known or suspected breast or genital tract cancer; history of or active arterial or venous thromboembolism or severe thrombophlebitis; porphyria.
Special Warnings and Precautions: Lutigest® should be discontinued if any of the following conditions are suspected: myocardial infarction, cerebrovascular disorders, arterial or venous thromboembolism, pulmonary embolism, thrombophlebitis or retinal thrombosis. Lutigest® should be used cautiously in patients with mild to moderate hepatic dysfunction. Patients with a history of depression should be closely observed. Progesterone may cause some degree of fluid retention, therefore, conditions that might be influenced by this factor require careful observation (e.g. Epilepsy, migraine, asthma, cardiac or renal dysfunction). A decrease in insulin sensitivity and thereby in glucose tolerance has been observed in a small number of patients on oestrogen-progestogen combination drugs, so diabetic patients should be carefully observed while receiving progesterone therapy. Sex steroid use may increase the risk of retinal vascular lesions and to prevent these complications, caution is to be taken in users >35 years, in smokers, and in those with risk factors for atherosclerosis. Use should be terminated in case of transient ischemic events, appearance of sudden severe headaches, or vision impairments related to papillary oedema or retinal haemorrhage. Abrupt discontinuation of progesterone dosing may cause increased anxiety, moodiness, and increased sensibility to seizures.
Side effects: Common: headache, abdominal distension, abdominal pain, nausea, uterine spasm. Uncommon: dizziness, insomnia, diarrhoea, constipation, urticaria, rash, vulvovaginal disorders, vaginal mycosis, breast disorders, pruritus genital, peripheral oedema.
Prescribers should consult the summary of product characteristics in relation to other adverse reactions.
Special precautions for storage: Store in the original container to protect from light. This medicinal product does not require any special temperature storage conditions.
Presentation: Alu blisters of 3 vaginal tablets. The blisters are available in cartons with 21 vaginal tablets with 1 vaginal applicator.

Marketing Authorisation Number: PL 03194/0103

Marketing Authorisation Holder: Ferring Pharmaceuticals Ltd. Drayton Hall, Church Road, West Drayton, UB7 7PS, UK.
Legal category: POM

Basic NHS price: £19.50 per pack of 21 tablets

Date of preparation: May 2020

Lutigest® is a registered trademark. **PI Job Code:** UK-LUG-2000002

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**