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: 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: Hypersensitivity to the active substance or any excipients; undiagnosed vaginal bleeding; known missed abortion 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: Discontinue Lutigest® if any of the following conditions are suspected: myocardial infarction, cerebrovascular disorders, arterial or venous thromboembolism, pulmonary embolism, thrombophlebitis or retinal thrombosis. Use with caution in mild to moderate hepatic dysfunction. Closely observe patients with a history of depression - consider discontinuation if symptoms worsen. Progesterone may cause some degree of fluid retention - carefully observe conditions that might be affected (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, therefore carefully observe diabetic patients receiving progesterone therapy. Sex steroid use may increase the risk of retinal vascular lesions therefore, caution in users >35 years, in smokers, and in those with risk factors for atherosclerosis. Terminate use 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.
Interactions: Inducers of cytochrome P450-3A4 e.g. rifampicin, carbamazepine, St Johns' Wort may increase elimination and therefore decrease progesterone bioavailability. Inhibitors of cytochrome P450-3A4 e.g. ketoconazole may decrease elimination and therefore increase progesterone bioavailability. It is recommended not to use Lutigest® with other vaginal products e.g. anti-fungal products as this may alter progesterone release and absorption form the vaginal tablet.
Pregnancy: Only indicated during the first trimester of pregnancy as part of an ART regimen. Limited and inconclusive data on risk of congenital anomalies following intrauterine exposure during pregnancy.
Breastfeeding: Do not use during lactation.
Side effects: Common and serious uncommon/frequency unknown AEs reported here. Consult the Summary of Product Characteristics for full information. Common: headache, abdominal distension, abdominal pain, nausea, uterine spasm. Serious uncommon: urticaria, peripheral oedema. Serious frequency unknown: Hypersensitivity reactions.
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: July 2023

Lutigest® is a registered trademark. **PI Job Code:** UK-LUG-2300003

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**