PRESCRIBING INFORMATION UTROGESTAN VAGINAL (progesterone) 200mg CAPSULES

For full product information, including side effects, precautions and contraindications, please consult the Summary of Product Characteristics (SmPC).

Presentation: Each soft vaginal capsule contains 200 mg progesterone (micronised). Slightly yellow, ovoid (approximately 15.1 mm x 9.1 mm) soft vaginal capsule, containing a whitish oily suspension.

Indication: Utrogestan Vaginal 200mg is indicated in adult women for supplementation of the luteal phase during Assisted Reproductive Technology (ART) cycles and for the prevention of preterm birth in women with a singleton pregnancy who have a short cervix (mid-trimester sonographic cervix ≤25mm) and/or a history of spontaneous preterm birth.

Posology and method of administration: For supplementation of the luteal phase during ART cycles the recommended dose is 600 mg/day given in three divided doses, one in the morning, one at midday and the third at bedtime. The treatment is started no later than the third day after oocyte retrieval. If pregnancy has been confirmed, continue treatment until at least the 7th week of pregnancy and not later than the 12th week of pregnancy. For prevention of preterm birth in women with a singleton pregnancy who have a short cervix and/or a history of spontaneous preterm birth, the recommended dosage is 200 mg per day in the evening at bedtime from around week 20 to week 34 of pregnancy. Each capsule of Utrogestan Vaginal 200mg must be inserted deep into the vagina.

Contraindications: Hypersensitivity to the active substance, soya, peanut or to any of the excipients; jaundice, severe hepatic dysfunction; undiagnosed vaginal bleeding; mammary or genital tract carcinoma; thrombophlebitis; thromboembolic disorders; cerebral haemorrhage; porphyria, missed abortion, premature rupture or membranes (PPROM).

Warnings and Precautions: It must only be administrated by the vaginal route. A complete medical examination must be performed before starting the treatment and regularly during the treatment. Utrogestan Vaginal 200mg capsules are not suitable as a contraceptive and must only be used in accordance with the indications. In rare cases, the use of micronised progesterone during the second and third trimester of pregnancy may lead to the development of gravidic cholestasis or hepatocellular liver disease. Treatment should be discontinued upon diagnosis of a missed abortion. Warning specific for supplementation of the luteal phase during Assisted Reproductive Technology cycles: Utrogestan Vaginal should only be used during the first three months of pregnancy and must only be administrated by vaginal route. It is not intended to treat an imminent premature delivery. For preterm birth, the risks and benefits of the options available, should be discussed with the patient. Premature rupture of membranes (PPROM) should be excluded. Should rupture of membranes occur during treatment, further treatment with Utrogestan Vaginal 200mg should be discontinued. Utrogestan Vaginal contains soyabean lecithin and may cause hypersensitivity reactions (urticarial and anaphylactic shock) in hypersensitive patients. As there is a possible relationship between allergy to soya and allergy to peanut, patients with peanut allergy must avoid using Utrogestan Vaginal. Utrogestan Vaginal contains highly refined sunflower oil, for which the incidence of hypersensitivity is very rare in adults.

Interactions: Drugs known to induce the hepatic CYP450-3A4 such as barbiturates, anti-epileptic agents (phenytoin, carbamazepine), rifampicin and also herbal products containing St. John's wort (Hypericum perforatum) may increase the elimination of progesterone. Ketoconazole and other inhibitors of CYP450-3A4 may increase the plasma exposure of progesterone.

Fertility, pregnancy and lactation: No association has been found between the maternal use of natural progesterone in early pregnancy and foetal malformations. Utrogestan Vaginal 200mg capsules is not indicated during breast- feeding. Detectable amounts of progesterone enter the breast milk. As this medicinal product is indicated to support luteal deficiency in subfertile or infertile women, there is no deleterious known effect on fertility.

Effect on ability to drive and use machines: This medicine has no or negligible influence on the ability to drive and use machines. However, dizziness or fatigue may occur in some individuals. If affected, patients should not drive or operate machines.

Undesirable effects: vaginal haemorrhage, vaginal discharge, pruritus, fatigue, burning sensation and dizziness occur at a frequency not known (cannot be estimated from the available data). Please refer to the SmPC for further information.

Overdose: Symptoms may include somnolence, dizziness, euphoria, or dysmenorrhoea. Treatment is observation and if necessary symptomatic and supportive measures should be provided.

Legal Category: POM **Marketing Authorisation Number:** PA 22624/001/001 **Marketing Authorisation Holder:** Besins Healthcare Ireland Limited, Level 4, Block 4 Custom House Plaza, International Financial Services Centre, Harbourmaster Place, Dublin 1, D01 A9N3, Ireland **Date of Preparation:** March 2026 MAT-PROMO-UTV-0098

Further information is available upon request or in the SmPC

Adverse events should be reported.
Reporting forms and information can be found at www.hpra.ie
Adverse events should also be reported to Besins Healthcare (UK) Ltd, Drug Safety on 01-4004466 or Email: drugsafety@besins-healthcare.com