PRESCRIBING INFORMATION UTROGESTAN VAGINAL (progesterone) 200 mg CAPSULES

For full prescribing 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). **Indication:** In women for supplementation of the luteal phase during Assisted Reproductive Technology (ART) cycles. Prevention of preterm birth in women with a singleton pregnancy who have a short cervix (mid-trimester sonographic cervix ≤25 mm) 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 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 of membranes (PPROM), allergy to peanuts or soya. **Warnings and Precautions for use**: 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 capsules are not suitable as a contraceptive. 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. For PTB 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 should be discontinued, Treatment should be discontinued upon diagnosis of a missed abortion. Utrogestan vaginal capsules contain soya 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 peanuts, patients with peanut allergy should avoid using Utrogestan vaginal capsules. **Interactions:** Utrogestan vaginal 200mg capsules may interfere with the effects of bromocriptine and may raise the plasma concentration of ciclosporin. This medicine may affect the laboratory tests of hepatic and/or endocrine functions. Metabolism of Utrogestan vaginal 200mg capsules is accelerated by rifamycin (such as rifampicin) medicines and antibacterial agents. The metabolism of progesterone by human liver microsomes was inhibited by ketoconazole (a known inhibitor of cytochrome P450 3A4). These data therefore suggest that ketoconazole may increase the bioavailability of progesterone. The clinical relevance of this in vitro finding is unknown. **Pregnancy and lactation:** No association has been found between the maternal use of natural progesterone in early pregnancy and foetal malformations. Detectable amounts of progesterone enter the breast milk. Utrogestan vaginal capsules are not indicated during breast- feeding. 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 machine:** Utrogestan Vaginal Capsules has negligible influence on the ability to drive and use machines. **Undesirable effects:** vaginal haemorrhage, vaginal discharge, pruritus occur and burning sensation at a frequency not known (cannot be estimated from the available data). **Overdose:** Symptoms may include somnolence, dizziness, euphoria, or dysmenorrhoea. Treatment is observation and if necessary symptomatic and supportive measures should be provided.

NHS Price: 21 capsules supplied with 21 disposable applicators £21. **Legal category:** POM. **Marketing Authorisation Number:** PL 28397/0005. **Marketing Authorisation Holder:** Besins Healthcare, Rue Washington 80, 1050 Ixelles, Belgium. **Date of preparation of Prescribing Information:** March 2024 UTV/2024/003

Adverse events should be reported.
Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.
Adverse events should also be reported to Besins Healthcare (UK) Ltd, Drug Safety on
0203 862 0920 or Email: pharmacovigilance@besins-healthcare.com