PRESCRIBING INFORMATION UTROGESTAN VAGINAL (progesterone) 200mg and 300mg CAPSULES

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

Presentation: Utrogestan vaginal 200mg- soft capsule contains 200 mg progesterone (micronised) with applicators; Utrogestan vaginal 300mg- soft capsule contain 300mg progesterone (micronised). **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. Utrogestan vaginal 300mg is indicated in adult women for supplementation of the luteal phase during Assisted Reproductive Technology (ART) cycles. **Posology and method of administration:** Utrogestan vaginal 200mg: 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.
Utrogestan vaginal 300mg: the recommended dose is 600 mg/day, given in two divided doses, one in the morning and the other at bedtime. The treatment is started not later than the third day after oocyte retrieval day and is continued until at least the 7th week of pregnancy and not later than the 12th week of pregnancy or until menstruation begins. Each capsule of Utrogestan Vaginal 300mg must be inserted deep into the vagina. **Contraindications:** For Utrogestan vaginal 200mg: 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. For Utrogestan vaginal 300mg: 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, allergy to nuts or soya. **Warnings and Precautions:** For Utrogestan vaginal 200mg: 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. 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 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. Treatment should be discontinued upon diagnosis of a missed abortion. Utrogestan vaginal 200mg 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 200mg capsules. For Utrogestan vaginal 300mg, it must only be administrated by the vaginal route. Any vaginal bleeding should always be investigated. A complete medical examination must be performed before starting the treatment and regularly during the treatment. Utrogestan vaginal 300mg capsules are not suitable as a contraceptive. Utrogestan vaginal 300 mg is not intended to treat an imminent premature delivery. 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. Glucose tolerance may be impaired during progesterone treatment, and more frequent monitoring should be performed. Progesterone has been linked to an increase in Type 2 diabetes, and adjustments in the medication of diabetes-treated patients may be required. Utrogestan vaginal 300mg 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 300mg capsules. **Interactions:** Utrogestan vaginal 200mg and 300mg 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 and 300mg 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 suggest that ketoconazole may increase the bioavailability of progesterone. The clinical relevance of this in vitro finding is unknown. **Fertility, 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 200mg and 300mg 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 machines:** Utrogestan vaginal 200mg and 300mg have negligible influence on the ability to drive and use machines. **Undesirable effects:** vaginal haemorrhage, vaginal discharge, pruritus and burning sensation occur at a frequency not known (cannot be estimated from the available data), in very rare cases, an anaphylactic reaction may occur (in <1/10000). **Overdose:** Symptoms may include somnolence, dizziness, euphoria, or dysmenorrhoea. Treatment is observation and if necessary symptomatic and supportive measures should be provided.

NHS List Price: For Utrogestan vaginal 200mg 21 capsules supplied with 21 disposable applicators £21.00; and for Utrogestan vaginal 300mg 15 capsules £18.50 **Legal Category:** POM **Marketing Authorisation Number: PA Marketing** Utrogestan vaginal 300mg PL 28397/0012. Utrogestan vaginal 200mg PL 28397/0005. **Authorisation Holder:** Besins Healthcare, 80 Rue Washington, 1050 Ixelles, Belgium **Date of Preparation:** June 2024 MAT-PROMO-UTV-0006

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@besinshealthcare.com