

PRESCRIBING INFORMATION

PROMETRIUM (progesterone) 400mg SOFT VAGINAL CAPSULES

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

Presentation: Prometrium 400mg soft vaginal capsules, each capsule contains 400mg of progesterone. **Indication:** Prometrium 400mg soft vaginal capsules is indicated for the prevention of miscarriage in women presenting with bleeding in the first trimester of pregnancy and who have a history of recurrent miscarriages. **Posology and method of administration:** Each capsule must be inserted deep into the vagina. Recommended dose is 400mg twice a day. Treatment should be initiated during the first trimester of pregnancy, at first sign of vaginal bleeding and should continue to the 16th week of gestation. **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, allergy to nuts or soya. **Warnings and Precautions:** Prometrium 400mg soft vaginal capsules should only be used up to the 16th week of pregnancy and must only be administered vaginally. Prometrium 400mg soft vaginal capsules is not suitable as a contraceptive. Treatment should be discontinued upon diagnosis of a missed abortion. Any vaginal bleeding should always be investigated. Contains soybean 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 should avoid using Prometrium 400mg soft vaginal capsules. A complete medical examination must be performed before starting the treatment and regularly during the treatment. **Interactions:** May interfere with the effects of bromocriptine and may raise the plasma concentration of ciclosporin. May affect the laboratory tests of hepatic and/or endocrine functions. Metabolism is accelerated by rifamycin medicines and antibacterial agents. **Fertility, pregnancy and lactation:** No association has been found between the maternal use of natural progesterone in early pregnancy and foetal malformation. Prometrium 400mg soft vaginal capsules is not indicated during breastfeeding. Detectable amounts of progesterone enter the breast milk. As this medicinal product is indicated to prevent miscarriage in women, there is no known deleterious

effect on fertility. **Effects on ability to drive and use machines:** Can have a moderate influence on the ability to drive and use machines. **Undesirable effects:** local intolerance (burning, itching or oily discharge) has been observed, but the incidence is extremely rare. When used as recommended, transient fatigue or dizziness may occur within 1 to 3 hours of taking the medicine. Pruritis, vaginal discharge, vaginal haemorrhage and burning sensation have been reported, the frequency of which is unknown. **Overdose:** symptoms of overdosage may include somnolence, dizziness, euphoria or dysmenorrhoea. Treatment is observation and if necessary, symptomatic and supportive measures should be provided.

NHS List Price: Prometrium 400mg soft vaginal capsules £20.00 for 15 capsules. **Legal Category:** POM **Marketing Authorisation Number:** PL 28397/0014. **Authorisation Holder:** Besins Healthcare, 80 Rue Washington, 1050 Ixelles, Belgium **Date of Preparation:** January 2025 MAT-PROMO-PTM-0003

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
Email: pharmacovigilance@besins-healthcare.com