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Prescribing information for Prometrium 400mg soft vaginal capsules can be found on the last page. Adverse event reporting can be found at the bottom of the last page.

prometrium progesterone 400mg soft vaginal capsules

BESINS HEALTHCARE By your side, for life

Threatened and recurrent miscarriage: clinical need, emotional impact and treatment guidance

Background

Miscarriage is the most common pregnancy complication.[1] About 15–25% of pregnant women miscarry during the first trimester.[2,3] An estimated 250,000 pregnancies end through miscarriage every year in the UK.[1]

About 1 in 100 women experience recurrent miscarriages, which are defined as occurring in at least three consecutive pregnancies.[5]

A global systematic review and meta-analysis of 29 studies with 35,375 participants reported that 32.5% of women experienced anxiety, 30.1% depression and 33.6% stress within six weeks of a miscarriage.[6]

Healthcare professionals should correct misconceptions held by patients and their partners such as: that miscarriage is rare; that lifting heavy objects or previous contraceptive use caused the pregnancy loss; or that there are no effective treatments to prevent miscarriage.[3]

Early pregnancy loss accounts for more than 50,000 hospital admissions in the UK annually.[4]

The risk of miscarriage increases by about 10% for each additional miscarriage.[3] The likelihood of miscarriage rises from 11% among women with no history of miscarriage to 42% in women with at least three previous miscarriages.[3]

During a multicentre, prospective cohort study of 737 patients with early pregnancy loss, 338 women completed the Hospital Anxiety and Depression Scale (HADS) after 9 months. Of the 537 women who experienced miscarriage, 249 patients completed the HADS 9 months after miscarriage: 18% met the criteria for post-traumatic stress disorder; 17% for moderate or severe anxiety; and 6% for moderate or severe depression.[7]

Women may not tell their family, close friends or partners about pregnancy loss. So, miscarriage can lead to a sense of isolation.[3]

To explore ways to support your patients after they have been prescribed Prometrium, scan the QR code for the Besins Patient Support Website. You can also scan the QR code for quick access to the Besins Patient Support Card.

PATIENT WEBSITE

Please Scan to access the Besins patient website

PATIENT SUPPORT CARD

Please Scan to access the Besins patient support card

By scanning these QR codes, you will be directed to a Besins Healthcare UK website designed for patients who have been prescribed Prometrium.

Scan Here to visit the Health Professional Academy Hub, a promotional hub sponsored by Besins Healthcare.

Treatment guidance

Guidelines published by NICE,[4] the Royal College of Obstetricians and Gynaecologists[8] and the European Society of Human Reproduction and Embryology[9] support using progesterone in women with a history of recurrent miscarriages who present with bleeding during the first trimester of pregnancy.

Prometrium (progesterone) 400mg soft vaginal capsules is the UK's first and only progesterone licensed to prevent miscarriage in women with a history of recurrent miscarriage who present with bleeding during the first trimester. The recommended dose is 400 mg twice a day (morning and night). 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.[10]

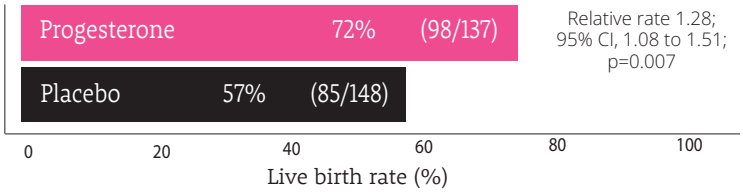
The PRISM trial[11]

The PRISM trial randomised 4153 women, recruited at 48 hospitals in the UK, to receive soft vaginal capsules, manufactured by Besins Healthcare, containing either 400 mg of progesterone (2079 women) or placebo (2074 women) twice daily. Treatment lasted from the time at which the woman presented with bleeding until 16 weeks of gestation.[11]

Progesterone vaginal capsules did not significantly increase the overall incidence of live births after at least 34 weeks of gestation, which was the study's primary outcome. The incidence of live births after at least 34 weeks of gestation was 75% in the progesterone group and 72% with placebo (relative rate 1.03; 95% confidence interval [CI], 1.00 to 1.07; p=0.08).[11]

In a prespecified subgroup of women with three or more first trimester miscarriages, the incidence of live births after at least 34 weeks of gestation was 72% in the progesterone 400mg twice daily group and 57% in the placebo group (absolute increase of 15%; relative rate 1.28; 95% CI, 1.08 to 1.51; p=0.007).[11]

Live birth rate (%) in women with at least three previous miscarriages



There was no significant difference in the percentage of participants in the PRISM trial who had either a maternal or neonatal serious adverse event (5% in each group) or the percentage of babies who had neonatal congenital abnormalities (3.4% in each group) between the progesterone and placebo arms.[11]

Safety information

Prometrium 400mg soft vaginal capsules 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.[10]

Some Prometrium users report local intolerance (burning, itching or oily discharge). When used as recommended, transient fatigue or dizziness may occur within 1 to 3 hours of taking Prometrium. Vaginal discharge and haemorrhage have been reported (unknown frequency).[10]

Please consult the Summary of Product Characteristics for further information.

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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

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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