Prescribing Information
Utrogestan (micronised progesterone) 100 mg capsules

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

Presentation: Round, slightly yellow soft capsule, containing whitish oily suspension. Each capsule contains 100 mg micronised progesterone. **Indication:** Adjunctive use with oestrogen in post- menopausal women with an intact uterus as hormone replacement therapy (HRT). **Dosage and administration:** In women receiving estrogen replacement therapy there is an increased risk of endometrial cancer which can be countered by progesterone administration. The recommended dose is 200 mg daily at bedtime for twelve days in the last half of each therapeutic cycle (beginning on Day 15 of the cycle and ending on Day 26). Withdrawal bleeding may occur in the following week. Alternatively, 100 mg can be given at bedtime from Day 1 to Day 25 of each therapeutic cycle, withdrawal bleeding being less with this treatment schedule. For initiation and continuation of treatment of postmenopausal symptoms, the lowest effective dose for shortest duration should be used. Dose for older people is the same. Not indicated in pre-pubescent children. Oral capsules should not be taken with food as this increases the bioavailability of micronised progesterone and should be taken at bedtime. **Contraindications:** When used in conjunction with estrogens, Utrogestan should not be used in patients with any of the following conditions: Hypersensitivity to the active substance soya, peanut or to any of the excipients, known past or suspected breast cancer; known or suspected hormone-dependent malignant tumours (e.g endometrial cancer); undiagnosed vaginal (genital) bleeding; untreated endometrial hyperplasia; previous or current thromboembolism (e.g. deep venous thrombosis, pulmonary embolism, thromboembolic disorders) or thrombophlebitis; known thrombophilic disorders (e.g. protein c, protein S, or antithrombin deficiency); active or recent arterial thromboembolic disease (e.g., angina pectoris, myocardial infarction); acute liver disease or history of liver disease as long as liver function tests have failed to return to normal; porphyria; cerebral haemorrhage has been observed with synthetic progestogens; breast- feeding. **Warnings and Precautions:** Utrogestan is not suitable as a contraceptive and must only be used in accordance with the indications. For the treatment of postmenopausal symptoms, HRT should only be initiated for symptoms that adversely affect quality of life. A careful appraisal of the risks and benefits should be undertaken at least annually and HRT should only be continued as long as the benefit outweighs the risk.. Before initiating or reinstituting HRT, a complete personal and family medical history should be taken. During treatment, periodic check-ups are recommended. Women should be advised what changes in their breast should be reported to their doctor or nurse. Investigations, including appropriate imaging tools, e.g. mammography, should be carried out in accordance with currently accepted screening practices, modified to the clinical needs of the individual. Patients should be closely supervised if any of the following conditions are present, have occurred previously and/or have been aggravated during pregnancy or previous hormone treatment since they may recur or be aggravated during treatment with Utrogestan 100 mg capsules; leiomyoma (uterine fibroids) or endometriosis; risk factors for thromboembolic disorders, risk factors for oestrogen dependent tumours (e.g. 1st degree heredity for breast cancer), hypertension, liver disorders (e.g. liver adenoma); diabetes mellitus with or without vascular involvement; cholelithiasis; migraine or severe headache; systemic lupus erythematosus; a history of endometrial hyperplasia; epilepsy; asthma; otosclerosis; fluid retention (e.g., cardiac, disease, renal disease); depression; photosensitivity. Therapy should be immediately discontinued in case a contra-indication is discovered and in the following situations: jaundice or deterioration in liver function, significant increase in blood pressure, new onset of migraine- type headache, pregnancy, sudden or gradual, partial or complete loss of vision; venous or thrombotic thromboembolic accidents regardless of the territory; proptosis or diplopia, papilloedema, retinal vascular lesions. Endometrial hyperplasia and carcinoma; the addition of progesterone for at least 12 days per month/28 day cycle or continuous combined estrogen-progestogen therapy in non-hysterectomised women prevents the excess risk associated with estrogen-only HRT. If breakthrough bleeding or spotting appears after some time on therapy, or continues after treatment has been discontinued, the reason should be investigated. Breast cancer; the overall evidence suggests an increased risk of breast cancer in women taking combined estrogen-progestogen and possibly also estrogen-only HRT, that is dependent on the duration of taking HRT. The excess risk becomes apparent within a few years of use but returns to baseline within a few (at most five) years after stopping treatment. HRT, especially estrogen- progestogen combined treatment, increases the density of mammographic images which may adversely affect the radiological detection of breast cancer. Ovarian cancer; epidemiological evidence from a large meta- analysis suggests a slightly increased risk in women taking estrogen-only or combined estrogen-progestogen HRT, which becomes apparent within 5 years of use and diminishes over time after stopping. Venous Thromboembolism (VTE); HRT is associated with a 1.3-3-fold risk of developing VTE. The occurrence of such an event is more likely in the first year of HRT than later. If prolonged immobilisation is to follow elective surgery temporarily stopping HRT 4 to 6 weeks earlier is recommended. Women already on chronic anticoagulant treatment require careful consideration of the benefit-risk of use of HRT. If VTE develops after initiating therapy, the drug should be discontinued. Patients should be told to contact their doctors immediately when they are aware of a potential thromboembolic symptom. The relative risk of coronary artery disease during use of combined estrogen + progestogen HRT is slightly increased. Combined estrogen-progestogen and estrogen-only therapy are associated with an up to 1.5-fold increase in risk of ischaemic stroke. HRT use does not improve cognitive function. There is some evidence of increased risk of probable dementia in women who start using continuous combined or estrogen-only HRT after the age of 65. Utrogestan 100 mg capsules contain soybean lecithin and may cause hypersensitivity reactions (urticaria 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 this medicine. Utrogestan contain highly refined oil, for which the incidence of hypersensitivity is very rare in adults. **Interactions:** Progestogens may affect the treatment balance of diabetes and an adjustment in anti-diabetic dosage may be required. Progesterone may: enhance or weaken the anticoagulant effect of coumarins and prevent the anticoagulant effect of phenindione; increase the plasma concentration of tizanimide and ciclosporin and risk of toxicity; interfere with the effects of bromocriptine, enhance the arrhythmogenicity of bupivacaine; alter results of liver and/or endocrine function tests; prevent oxidation of some benzodiazepine derivatives such as diazepam, chlordiazepoxide and alprazolam and to induce glucuronidation of oxazepam and lorazepam. Drugs that may increase metabolism of progesterone: Perampanel or topiramate; some antibiotics (ampicillin, amoxicillin and tetracycline) may lower plasma concentrations of steroids; rifampicin and rifabutin; epilepsy medicines (phenytoin, phenobarbital, carbamazepine, eslicarbazepine, oxcarbazepine and primidone/rufinamide) not valproic acid; herbal medicinal products containing St John's wort (Hypericum perforatum); antiretroviral medicines (protease blockers): darunavir, nelfinavir, fosamprenavir, lopinavir; bosentan; aprepitant. Antifungal medicines (fluconazole, itraconazole, ketoconazole, voriconazole), immunosuppressants (tacrolimus), statins (atorvastatin, rosuvastatin) and monoamine oxidase (MAO) inhibitors (selegiline) may prevent the metabolism of progesterone which leads to an increase in the bioavailability of progesterone. **Fertility, Pregnancy and lactation:** If pregnancy occurs medication, should be withdrawn immediately. The data relating to inadvertent foetal exposure to combinations of estrogens + progesterone indicate no teratogenic or foetotoxic effect. Prescription of progesterone beyond the first trimester may reveal gravidic cholestasis. Utrogestan 100mg is Not indicated during breast-feeding. Progesterone is distributed into breast milk. **Effects on ability to drive and use machines:** Utrogestan 100mg May cause drowsiness or dizziness; therefore care should be taken when driving or using machines. Taking the capsules at bedtime helps avoids these drawbacks. **Undesirable effects:** Post marketing experience, from oral administration of progesterone: Common adverse reactions (≥1/100; <1/10): occur with this medicine: weight fluctuation, insomnia, dizziness, headache, somnolence, abdominal distension, abdominal pain, nausea, pruritus, intermenstrual bleeding, vaginal haemorrhage, menstruation irregular, amenorrhoea, metrorrhagia, breast pain and breast tenderness, breakthrough bleeding or irregular withdrawal bleeding, fatigue, malaise. Uncommon adverse reactions (≥1/1000; <1/100): occur with this medicine: thromboembolic disorder, fluid retention, agitation, anxiety, apathy, depression, disorientation, mood swings, nervousness, amnesia, migraine, paraesthesia, speech disorder, syncope, visual disturbance, tinnitus, vertigo, palpitations, tachycardia, haemorrhage, hot flush, hypotension, thrombotic events (mainly when taken in combination with estrogen), dyspnoea, constipation, diarrhoea, vomiting, non-severe and reversible liver disorders, cholestatic jaundice, acne, alopecia, erythema, hyperhidrosis, rash, urticaria, arthralgia, back pain, limb discomfort, muscle spasms, myalgia, abnormal withdrawal bleeding, breast discomfort, endometrial hyperplasia, vaginal discharge, vulvovaginal discomfort, menstrual cycle abnormal, mastodynia, hirsutism, asthenia, chest discomfort, chest pain, oedema. Rare adverse events (≥1/10000; <1/1000): occur with this medicine: eye irritation, loss of appetite, dysuria, anaphylactoid reactions. Please refer to the SmPC for further information. **Overdose:** Symptoms may include drowsiness, somnolence, or fatigue. Treatment of overdosage consists of discontinuation of Utrogestan together with institution of appropriate symptomatic and supportive care

NHS Price: £6.60 for 30 capsules. **Legal category:** POM. **Marketing Authorisation Number:** PL 28397/0003. Marketing Authorisation Holder**:** Besins Healthcare, Rue Washington 80, 1050 Ixelles, Belgium. **Date of preparation of prescribing information:** March 2025 MAT-PROMO-UTO-0008

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