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Gepretix (progesterone) 100mg soft capsules. UK Prescribing Information
Please consult the full Summary of Product Characteristics (SmPC) before prescribing.

Presentation: Each capsule contains: 100mg Progesterone. Excipient(s) with known effect: soya bean lecithin**. Indication**: Gepretix 100mg soft capsules is indicated for adjunctive use with an oestrogen in post-menopausal women with an intact uterus, as hormone replacement therapy (HRT). **Dosage and administration:** For adults aged 18 years and over only. The recommended dose is 200mg 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, 100mg can be given at bedtime from Day 1 to Day 25 of each therapeutic cycle, withdrawal bleeding being less with this treatment schedule. This product is intended for oral use only. Gepretix should not be taken with food and should be taken at bedtime. **Contraindications:** hypersensitivity to progesterone, soybean lecithin, peanut or to any of the excipients, known, past or suspected breast cancer, known or suspected oestrogen-dependent malignant tumours (e.g. genital tract carcinoma), undiagnosed genital bleeding, previous or current thromboembolism disorders (e.g. deep venous thrombosis, pulmonary embolism) or thrombophlebitis, known thrombophilic disorders, acute liver disease, or a history of liver disease as long as liver function tests have failed to return to normal, porphyria, cerebral haemorrhage, breast-feeding. Please refer to SmPC for full details. **Special warnings and precautions for use:** HRT should only be initiated for post-menopausal symptoms that adversely affect quality of life. Appraisal of the risks and benefits should be undertaken at least annually. HRT should only be continued as long as the benefit outweighs the risk. Evidence regarding the risks associated with HRT in the treatment of premature menopause is limited. Due to the low level of absolute risk in younger women, however, the balance of benefits and risks for these women may be more favourable than in older women. Not suitable in confirmed pregnancy, in treatment of premature labour, as a contraceptive. Before initiating/reinstituting HRT, a complete personal and family medical history should be taken. Physical (including pelvic and breast) examination should be guided by this and by the contraindications and warnings for use. Periodic check-ups are recommended. Women should be advised what changes in their breasts should be reported. Investigations should be carried out in accordance with currently accepted screening practices, modified to the clinical needs of the individual. Conditions requiring supervision include: leiomyoma (uterine fibroids) or endometriosis, risk factors for thromboembolic disorders and/or oestrogen dependent tumours, hypertension, liver disorders, diabetes mellitus with or without vascular involvement, cholelithiasis, migraine or (severe) headache, systemic lupus erythematosus, history of endometrial hyperplasia, epilepsy, asthma, otosclerosis, depression, photosensitivity. Gepretix 100 mg soft capsules contain soybean lecithin and may cause hypersensitivity reactions. **Reasons for immediate withdrawal of therapy**: Therapy should be 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, proptosis or diplopia, papilloedema, retinal vascular lesions As there is a possible relationship between allergy to soya and allergy to peanut, patients with peanut allergy should avoid using Gepretix 100mg soft capsules. **Interactions:** *Enzyme inducers* known to induce hepatic CYP450-3A4 such as barbiturates, anti-epileptic agents (phenytoin, carbamazepine), rifampicin, phenylbutazone, bromcriptine, spironolactone, griseofulvin, some antibiotics (ampicillins, tetracyclines) and herbal products containing St. John's wort, (Hypericum perforatum) may increase metabolism and the elimination of progesterone. *Enzyme inhibitors*: Ketoconazole and other inhibitors of CYP450-3A4 such as ritonavir and nelfinavir may increase bioavailability of progesterone. *Immunosuppressants:* Progesterone may raise plasma concentration of ciclosporin. *Antisteroidal drugs:* Aminoglutethimide markedly reduces plasma concentrations of medroxyprogesterone acetate and megestrol. *Anticoagulants:* Progesterone may enhance or reduce anticoagulant effect of coumarins. Progesterone antagonises anticoagulant effect of phenindione. *Diabetic medications:* An adjustment in anti-diabetic dosage may be required for women treated concomitantly with progesterone. *Emergency contraceptives:* Concomitant use of ulipristal acetate with progesterone is expected to result in reduced efficacy of progesterone. *Other:* Progesterone may increase plasma concentration of diazepam, tizanidine. Terbinafine: Occasional reports of breakthrough bleeding when terbinafine is used concomitantly with progesterone. Progesterone may affect results of hepatic/endocrine function laboratory tests. **Fertility, Pregnancy, Lactation:** Fertility not relevant. Withdraw treatment immediately if pregnancy occurs. Not indicated while breastfeeding as progesterone is distributed into breast milk. **Driving.** May cause drowsiness, care should be taken when driving or using machines. **Undesirable effects:** serious effects: breast cancer risk, endometrial cancer risk, ovarian cancer, risk of VTE, risk of ischaemic stroke, depression, probable dementia, skin and subcutaneous disorders, including erythema multiforme, erythema nodosum and vascular purpura. Very common (≥1/10); abdominal bloating, abdominal pain, headache, dizziness, depression, breast tenderness, hot flushes, vaginal discharge, joint pain, urinary problems. Other reported adverse events of unknown frequency from extensive post-marketing experience include: abdominal pain, nausea, fatigue, headache, somnolence, dizziness, vaginal haemorrhage, pruritis. Please refer to SmPC for full details of other side effects. **Legal category:** POM. **Presentation and cost:** 30 capsules in a thermo-sealed blister (PVC/PE/PVDC/Aluminium) £4.62 **Marketing authorisation holder & number**: Exeltis Healthcare S.L. PL 44081/0009. **Date of first/ renewal of authorisation:** March 2023. **Date of preparation of prescribing information:** July 2023. Further information available from Exeltis UK Limited, Two Snowhill, 7th Floor, Birmingham, B4 6GA. EXE-I/IPR-GEP-1580 Date of preparation November 2024.

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 Exeltis UK Limited by email to uk.pharmacovigilance@exeltis.com