

PRESCRIBING INFORMATION (combined)

Femoston-conti 0.5 mg/2.5 mg film-coated tablets, Femoston-conti 1 mg/5 mg film-coated tablets, Femoston 1/10 mg film-coated tablets, Femoston 2/10 mg film-coated tablets (Estradiol and dydrogesterone)

Refer to the Summary of Product Characteristics for full information.

Indication: Femoston-conti 0.5 mg/2.5 mg and 1 mg/5 mg film-coated tablets; Hormone replacement therapy (HRT) for oestrogen deficiency symptoms in postmenopausal women at least 12 months since last menses. Femoston 1/10 mg and 2/10 mg film-coated tablets; Hormone replacement therapy (HRT) for oestrogen deficiency symptoms in postmenopausal women at least 6 months since last menses. Femoston-conti 1 mg/5 mg, Femoston 1/10 mg and 2/10 mg film-coated tablets are also indicated for the prevention of osteoporosis in postmenopausal women at high risk of future fractures who are intolerant of, or contraindicated for, other medicinal products approved for the prevention of osteoporosis. The experience in treating women older than 65 years is limited. **Presentation:** Femoston-conti 0.5 mg/2.5 mg film-coated tablets containing 0.5 mg oestradiol (as hemihydrate) and 2.5 mg dydrogesterone. Femoston-conti 1 mg/5 mg film-coated tablets containing 1 mg oestradiol (as hemihydrate) and 5 mg dydrogesterone. Femoston 1/10 mg film-coated tablets containing 1 mg oestradiol (as hemihydrate) or a combination of 1 mg oestradiol (as hemihydrate) and 10 mg dydrogesterone. Femoston 2/10 mg film-coated tablets containing 2 mg oestradiol (as hemihydrate) or a combination of 2 mg oestradiol (as hemihydrate) and 10 mg dydrogesterone. **Dosage and administration:** Femoston-conti 0.5 mg/2.5 mg and 1 mg/5 mg film-coated tablets; given as a continuous combined HRT every day without a break between packs. Dosage is one tablet per day for a 28 day cycle. Continuous combined treatment may be started depending on the time since menopause and severity of symptoms. Women experiencing a natural menopause should commence treatment 12 months after their last natural menstrual bleed. For surgically induced menopause, treatment may start immediately. Patients changing from a continuous sequential or cyclical preparation should complete the 28 day cycle and then change to Femoston-conti 0.5 mg/2.5 mg or 1 mg/5 mg film-coated tablets. Patients changing from another continuous combined preparation may start therapy at any time. Femoston 1/10 mg and 2/10 mg film-coated tablets; given as a continuous sequential HRT without a break between packs. For first 14 days of 28-day cycle, one tablet containing oestradiol taken daily; during the following 14 days one tablet containing oestradiol and dydrogesterone is taken. After a cycle of 28 days, on the 29th day, a new 28-day cycle begins. Women who are not taking HRT and who are amenorrhoeic, or those who switch from a continuous combined HRT treatment can start on any day. If transferring from a cyclic or continuous sequential HRT regimen, treatment should begin the day following completion of prior regimen. For initiation and continuation of treatment of postmenopausal symptoms, the lowest effective dose for the shortest duration should be used. Depending on the clinical response, the dosage can subsequently be adjusted. If a dose has been forgotten, it should be taken as soon as possible. If more than 12 hours have elapsed, treatment should be continued with the next tablet without taking the forgotten tablet. The likelihood of breakthrough bleeding or spotting may be increased. For oral use. Can be taken before or after food. Paediatric population: No relevant indication. **Contraindications:** Known, past or suspected breast cancer, known or suspected oestrogen-dependent malignant tumours, known or suspected progesterone-dependent neoplasms, undiagnosed genital bleeding, untreated endometrial hyperplasia, venous thromboembolism, known thrombophilic disorders, active or recent arterial thromboembolic disease, acute liver disease or a history of liver disease as long as liver function tests have failed to return to normal, porphyria, known hypersensitivity to the active substances or to any of the excipients, meningioma or history of meningioma. **Warning and precautions:** HRT should only be initiated for symptoms that adversely affect quality of life. In all cases, 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 re-instituting HRT, a complete physical 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. During treatment, periodic check-ups are recommended of a frequency and nature adapted to the individual woman. Women should be advised what changes in their breasts should be reported to their doctor or nurse. Carefully supervise if leiomyoma or endometriosis, risk factors for thromboembolic disorders or oestrogen-dependent tumours, hypertension, liver disorders, diabetes mellitus, cholelithiasis, migraine or severe headaches, systemic lupus erythematosus, history of endometrial hyperplasia, epilepsy, asthma, otosclerosis conditions are present or have previously occurred and/or have been aggravated during pregnancy or previous hormone treatment. The occurrence of meningiomas (single and multiple) has been reported in association with use of Femoston and Femoston-conti film-coated tablets. Patients should be monitored for signs and symptoms of meningiomas in accordance with clinical practice. If a patient is diagnosed with meningioma, any oestradiol/dydrogesterone containing treatment must be stopped. Tumour shrinkage has been observed after treatment discontinuation. Therapy should be discontinued in case a contraindication 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. Break-through bleeding and spotting may occur during the first months of treatment. If break-through bleeding or spotting appears after some time on therapy, or continues after treatment has been discontinued, the reason should be investigated. An increased risk of breast cancer has been reported that is dependent on the length of treatment. HRT can increase the density of mammographic images which

may affect radiological detection of breast cancer. The use of oestrogen-only or combined oestrogen-progestogen HRT has been associated with a slightly increased risk of ovarian cancer. HRT is associated with an increased relative risk of venous thromboembolism (VTE) i.e. deep vein thrombosis or pulmonary embolism. Patients with known thrombophilic states have an increased risk of VTE and HRT may add to this risk. HRT is therefore contraindicated in these patients. Generally recognised risk factors for VTE include: use of oestrogens, older age, major surgery, prolonged immobilisation, obesity (BMI > 30 kg/m²), pregnancy/postpartum period, systemic lupus erythematosus (SLE), and cancer. If VTE develops after initiating therapy, the drug should be discontinued. Oestrogens may cause fluid retention, and therefore patients with cardiac or renal dysfunction should be carefully observed. Relative risk of coronary artery disease is raised with oestrogen-progestogen therapy, but randomised controlled trials have not shown an increase with oestrogen-only therapy. The use of oestrogen-only and oestrogen progestogen therapy is associated with an up to 1.5-fold increased relative risk of ischaemic stroke. Women with pre-existing hypertriglyceridemia should be followed closely (risk of pancreatitis). Exogenous oestrogens may induce or exacerbate symptoms of hereditary and acquired angioedema. Certain endocrine tests may be affected. No evidence for improvement in cognitive function. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine. Oestrogen-progestogen combination treatment is not a contraceptive. **Interaction with other medicinal products:** The metabolism of oestrogens and progestogens may be increased by concomitant use of P450 enzymes such as anticonvulsants and anti-infectives. Ritonavir, nelfinavir and herbal preparations containing St. John's Wort may induce the metabolism of oestrogens and progestogens. Caution is warranted for co-administration with drug regimens containing ombitasvir/ paritaprevir/ritonavir and dasabuvir with or without ribavirin, glecaprevir/pibrentasvir or sofosbuvir/ velpatasvir/voxilaprevir. Clinically, an increased metabolism of oestrogens and progestogens may lead to decreased effect and changes in the uterine bleeding profile. Hormone contraceptives containing oestrogen have been shown to significantly decrease plasma concentrations of lamotrigine when co-administered due to induction of lamotrigine glucuronidation. This may reduce seizure control. Femoston 1/10 mg and 2/10 mg film-coated tablets; Oestrogens may inhibit CYP450 drug-metabolising enzymes via competitive inhibition, particularly substances such as tacrolimus and cyclosporine A, fentanyl and theophylline. This may lead to an increased plasma level of the affected substances up to toxic levels. Careful drug monitoring might be indicated and a dosage decrease of tacrolimus, fentanyl, cyclosporine A and theophylline may be necessary. **Pregnancy, Lactation and Fertility:** Not indicated during pregnancy or lactation. If pregnancy occurs withdraw treatment immediately. **Effects on ability to drive and use machines:** No influence on the ability to drive and/or to use machines. **Undesirable effects:** Very Common: Headache, abdominal pain, back pain, breast pain/tenderness. Common: Vaginal candidiasis, depression, nervousness, migraine, dizziness, nausea, vomiting, abdominal distention (including flatulence), allergic skin reactions (e.g. rash, urticaria, pruritus), menstrual disorders (including postmenopausal spotting, metrorrhagia, menorrhagia, oligo-/amenorrhoea, irregular menstruation, dysmenorrhoea), pelvic pain, cervical discharge, asthenic conditions (asthenia, fatigue, malaise), peripheral oedema, increased weight. Uncommon: Cystitis-like syndrome, increase in size of leiomyoma, hypersensitivity, influence on libido, venous thromboembolism, hypertension, peripheral vascular disease, varicose vein, dyspepsia, abnormal hepatic function, occasionally with jaundice, asthenia or malaise, and abdominal pain, gall bladder disorder, breast enlargement, premenstrual syndrome, decreased weight. Rare: Haemolytic anaemia, meningioma, steepening of corneal curvature, contact lenses intolerance, myocardial infarction, stroke, angioedema, vascular purpura, erythema nodosum, chloasma or melasma, which may persist when drug is discontinued, leg cramps. Possible risk factors: Breast cancer, ovarian and endometrial cancer, venous thromboembolism, coronary artery disease and ischaemic stroke. Other adverse reactions: Oestrogen dependent neoplasms both benign and malignant, e.g. endometrial cancer, ovarian cancer, increase in size of progesterone dependent neoplasms, e.g. meningioma, haemolytic anaemia, systemic lupus erythematosus, hypertriglyceridemia, probable dementia over the age of 65, chorea, exacerbation of epilepsy, steepening of corneal curvature, contact lenses intolerance, arterial thromboembolism, pancreatitis (in women with pre-existing hypertriglyceridemia), erythema multiforme, erythema nodosum, chloasma or melasma, which may persist when drug is discontinued, leg cramps, urinary incontinence, fibrocystic breast disease, uterine cervical erosion, aggravated porphyria, total thyroid hormones increased. **Legal Category: POM Marketing Authorisation Number:** Femoston 1/10 mg film-coated tablets PL 44081/0038; Femoston 2/10 mg film-coated tablets PL 44081/0037; Femoston-conti 0.5 mg/2.5 mg film-coated tablets PL 44081/0035; Femoston-conti 1 mg/5 mg film-coated tablets PL 44081/0036 **MAH:** Exeltis Healthcare S.L. Avda. de Miralcampo 7, Pol. Ind. Miralcampo 19200-Azuqueca de Henares (Guadalajara) Spain **NHS Price:** Femoston-conti £24.43 (84 tablets) & Femoston £16.16 (84 tablets) **Date of Revision of Prescribing Information:** July 2025 **Reference:** EXE-E/IPR-FEM-1827-v2. The SmPC for this product, including adverse reactions, precautions, contra-indications, and method of use can be found at: <http://www.mhra.gov.uk/Safetyinformation/Medicinesinformation/SPCandPILs/index.htm>

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 pharmacovigilance.uk@exeltis.com