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

Refer to the Summary of Product Characteristics for full information.

Presentation: Femoston-conti 0.5 mg/2.5 mg film-coated tablets containing 0.5 mg estradiol (as hemihydrate) and 2.5 mg dydrogesterone. Femoston-conti 1 mg/5 mg film-coated tablets containing 1 mg estradiol (as hemihydrate) and 5 mg dydrogesterone. Femoston 1/10 mg film-coated tablets containing 1 mg estradiol (as hemihydrate) or a combination of 1 mg estradiol (as hemihydrate) and 10 mg dydrogesterone. Femoston 2/10 mg film-coated tablets containing 2 mg estradiol (as hemihydrate) or a combination of 2 mg estradiol (as hemihydrate) and 10 mg dydrogesterone. **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. **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 not earlier than at least 12 months after their last natural menstrual bleed. For surgically induced menopause, treatment may start immediately. 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 estradiol taken daily; during the following 14 days one tablet containing estradiol and dydrogesterone is taken. 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. 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 progestogen-dependent neoplasms, undiagnosed genital bleeding, untreated endometrial hyperplasia, venous thromboembolism, known thrombophilic disorders, arterial thromboembolic disease, acute liver disease or a history of liver disease, porphyria, known hypersensitivity to the active substances or to any of the excipients. **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 and meningioma conditions are present or have previously occurred and/or have been aggravated during pregnancy or previous hormone treatment. 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 Investigate breakthrough bleeding. 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/m^2), 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. 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. Clinically, an increased metabolism of oestrogens and progestogens may lead to decreased effect and changes in the uterine bleeding profile. 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 recommended. 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, 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 progestogen 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.

Marketing Authorisation Holder: Mylan Products Ltd., 20 Station Close, Potters Bar, Herts, EN6 1TL, UK.
Marketing Authorisation Number: Femoston 1/10 mg film-coated tablets PL 46302/0035; Femoston 2/10 mg film-coated tablets PL 46302/0036; Femoston-conti 0.5 mg/2.5 mg film-coated tablets PL 46302/0037; Femoston-conti 1 mg/5 mg film-coated tablets PL 46302/0038

Basic NHS price: Femoston-conti £24.43 (84 tablets) & Femoston £16.16 (84 tablets)
Legal Category: POM
Date of Last Revision: October 2020
Veeva Reference: FEM-2020-0409

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 and from Mylan Medical Information, Building 4, Trident Place, Hatfield Business Park, Mosquito Way, Hatfield, Hertfordshire, AL10 9UL, phone no. 01707 853000, Email: info@mylan.co.uk

Adverse Drug Reactions 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 be reported to UK Pharmacovigilance, Mylan, Building 4, Trident Place, Hatfield Business Park, Mosquito Way, Hatfield, Hertfordshire, AL10 9UL, on phone no. +44 (0) 800 121 8267, Email: ukpharmacovigilance@mylan.com