Hormone Replacement Therapy: Cost Comparison

Could you prescribe Femoston®?

estradiol/dydrogesterone

ESTABLISHED HRT 25 YEARS* femoston IN THE MARKET FOR 25 YEARS*

HRT (Hormone Replacement Therapy)
*Source: IQVIA Midas via SMART worldwide 2019, Femoston launch date

The only HRT range with dydrogesterone

by Viatris Women's Healthcare

Visit our promotional website to find out more about our HRT range

www.mywayhub.co.uk

Treatment Navigator

Stock Availability

Experts Corner

Femoston® is indicated for estrogen deficiency symptoms in postmenopausal women at least 6 months since last menses and Femoston®-conti is indicated for estrogen deficiency symptoms in postmenopausal women at least 12 months since last menses.

*IQVIA Midas via SMART worldwide 2019, Femoston® launch date.

FEM-2022-0168 DOP:September 2022

VIATRIS

Patient case studies

The patient case studies are not intended to replace clinical decision making. The benefits and risks of HRT must be assessed and tailored to each individual patient. Below are some examples of other factors which should be considered when prescribing HRT.

Some factors to consider when prescribing HRT:[1–7]

- Benefits/risks of HRT
- Presence/absence of uterus
- Conditions which need supervision
- Type of hormone(s)
- Time since last menstrual period
- Patient choice
- Age of menopause
- Risk factors for VTE
- Need for contraception
- Severity of symptoms
- Malabsorption
- Migraines

Please note: Not all patients are suitable for oral HRT. The prescriber must make a clinical decision for each individual patient on whether they can be considered for oral therapy.

Emma, Age: 46

Situation: First visit to GP

Symptoms: No periods for 6 months, previously erratic periods, "brain fog", irritable, hot flushes

Concern: No personal history of breast disease, however, aunt had breast cancer at age 55†

Taking: Over-the-counter herbal remedies

femoston® estradiol / dydrogesterone

Initiate with: Femoston® 1/10 mg

KEY CONSIDERATIONS

1. Patient worried about the risk of breast cancer with HRT → assess patient's overall breast cancer risk and discuss benefit/risk profile of HRT
2. Although all systemic HRT increases the risk of breast cancer → consider the progestogen (see third page)

Deborah, Age: 52

Situation: 3-month HRT review

Prescribed: Sequential combined transdermal patch

Review notes: Symptoms improved, but experiencing androgenic side effects and patch causing irritation

femoston® estradiol / dydrogesterone

Consider: Femoston® 1/10, or 2/10 mg

KEY CONSIDERATIONS

1. Transdermal patch causing irritation → consider the route
2. Androgenic side effects → consider the progestogen

Jill, Age: 55

Situation: Visited GP twice before seeing a specialist now at 3-month HRT review

Prescribed: Continuous micronised progesterone & estradiol gel

Review notes: Symptoms improved, however, patient experiencing drowsiness due to the micronised progesterone[14] and needs to pay two prescription charges for treatment regime

femoston®-conti estradiol / dydrogesterone

Consider: Femoston®-conti 1/5 mg

KEY CONSIDERATIONS

1. Side effects → Consider the progestogen
2. Two prescription charges → continuous combined oral therapy only one charge for the patient

HRT: Hormone replacement therapy; VTE: Venous thromboembolism.

†*For full information on assessment of familial breast cancer risk, please refer to NICE Clinical Guideline [CG164] available at https://www.nice.org.uk/guidance/cg164*

What is the monthly cost** of treating patients with the most common combined HRT regimes?[8,9]

Table below contains some examples of the most commonly prescribed combined HRT regimes, and is not intended as a clinical prescribing guide. It is not an exhaustive list and note that other HRT options are available including, combinations using LNG 52mg IUS. Clinical prescribing should be guided by the clinical judgement and individual assessment of each patient.

Trade name(s) (Hormone content)	Elleste Duet™ (E2 1mg, 2mg) & (NETA 1mg)	Novofem® (E2 1mg) & (NETA 1mg)	Kliofem® (E2 2mg) & (NETA 1mg)	Kliovance® (E2 1mg) & (NETA 500mcg)	Femoston® (E2 1mg, 2mg) & (DYD 10mg)	Elleste Duet™ Conti (E2 2mg) & (NETA 1mg)	Femoston® -conti (E2 500mcg, 1mg) & (DYD 2.5mg, 5mg)	Evorel® + Utrogestan® (E2 50mcg) + (MP 100mg - 1 or 2 caps per day)[□]	Oestrogel® + Utrogestan® (E2 0.06% - 2 pumps per day) + (MP 100mg - 1 or 2 caps per day)[□]	Evorel® Sequi (E2 50mcg) & (NETA 170mcg)	Evorel® Conti (E2 50mcg) & (NETA 170mcg)
Route of administration											
Treatment regimen	Sequential combined therapy	Sequential combined therapy	Continuous combined therapy	Continuous combined therapy	Sequential combined therapy	Continuous combined therapy	Continuous combined therapy	Sequential/ continuous combined therapy	Sequential/ continuous combined therapy	Sequential combined therapy	Continuous combined therapy
Treatment duration	28 days										
Monthly cost**	£3.07	£3.81	£3.81	£4.40	£5.39	£5.67	£8.14	£3.88 + £4.10 = £7.98 £3.88 + £4.28 = £8.16	£4.20 + £4.10 = £8.30 £4.20 + £4.28 = £8.48	£11.09	£13.00

Novofem®, Kliofem® and Kliovance® are trade names of Novo Nordisk Limited; Utrogestan® and Oestrogel® are trade names of Besins Healthcare (UK) Ltd; Evorel®, Evorel® Sequi and Evorel® Conti are trade names of Theramex UK Limited

□Please refer to the Utrogestan® SmPC[14] for full information on how Utrogestan® is used within either a sequential or continuous combined HRT regime.

**These prices are based on 28 days of treatment taken from the MIMS HRT table.[9] Prices last accessed in September 2022. Some products are only available in either 1 or 3 month packs.

"But doctor, are all progestogens the same?"

- Overall evidence shows an increased risk of breast cancer in women taking combined estrogen-progestogen or estrogen-only HRT, that is dependent on the duration of taking HRT.[4–7]
- The Women's Health Initiative (WHI) study and a meta-analysis are consistent in finding an increased risk of breast cancer in women taking combined estrogen-progestogen for HRT that becomes apparent after about 3 (1–4) years.[4–7]

Additional results of observational studies and a meta-analysis from 2019, show that **different progestogens may have different risk profiles when it comes to breast cancer risk.**[10-13] >>

HRT: Hormone replacement therapy; LNG: Levonorgestrel; IUS: Intrauterine system; E2: Estradiol; NETA: Norethisterone; DYD: Dydrogesterone; MP: Micronised progesterone.

Oral =  Transdermal patch =  Gel = 

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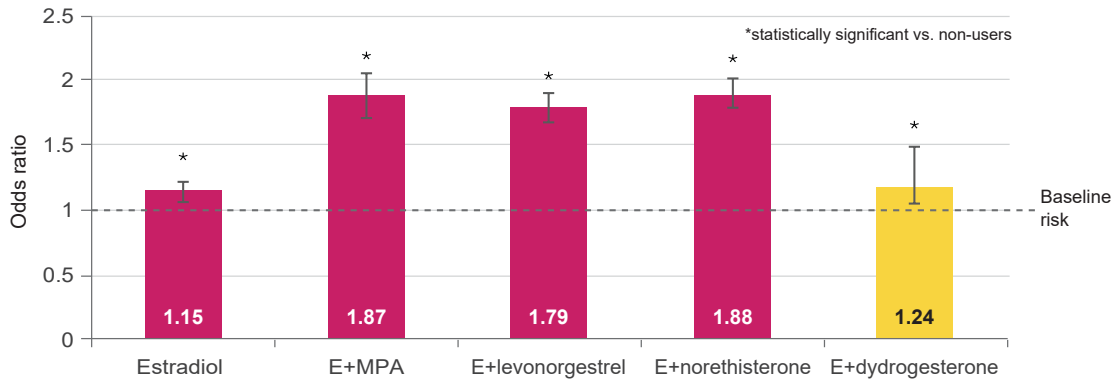
Breast cancer data[10,13]

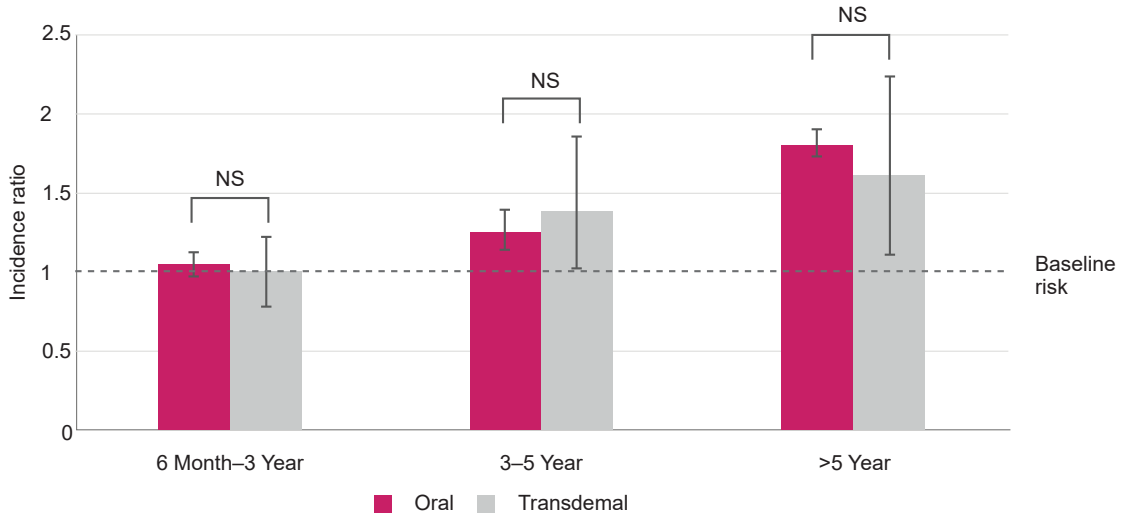
Odds ratios for breast cancer for recent users^ with long-term (≥ 5years use) use of HRT, by combination and progestogen component



^Recent users is defined as those with prescriptions more than one year and less than five years before the index date.
E: Estrogen; MPA: Medroxyprogesterone acetate.

Conclusion: A recent nested case-control study reported that in recent users^ with long-term use *(>5 years)*, amongst the combined progestogens, the increased risk was **highest for norethisterone** *(OR: 1.88, CI 1.79 to 1.99)* and **lowest for dydrogesterone** *(OR: 1.24, CI 1.03 to 1.48).*[13]

Standardised incidence ratio of invasive breast cancer among women using estrogen-progestogen therapy according to the route of administration and duration of use



NS: Non-significant

Conclusion: A Finnish Cohort study, which included 221,551 postmenopausal women, reported that there was **no difference between the route of administration (oral vs. transdermal)** when it came to breast cancer risk.[10]

HRT: Hormone replacement therapy.

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The Femoston® Range – available in 4 preparations

The choice of Femoston® preparation is an individual decision between the patient and clinician. The choice depends upon their symptoms severity, benefit/risk profile and personal choice and preference.

femoston® 2 mg / 10 mg
estradiol / dydrogesterone

Depending on clinical response the dosage can subsequently be adjusted

femoston® 1 mg / 10 mg
estradiol / dydrogesterone

- Use Femoston® 1/10 and 2/10 for women with estrogen deficiency symptoms, whose last menstrual period was more than 6 months ago
- The dosage can be adjusted depending on clinical response and the preparation continued if well tolerated

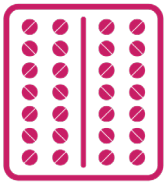
femoston® conti 1 mg / 5 mg
estradiol / dydrogesterone

Depending on clinical response the dosage can subsequently be adjusted

femoston® conti 0,5 mg / 2,5 mg
estradiol / dydrogesterone
Ultra low dose

- Use Femoston®-conti 1/5 and 0.5/2.5 for women with estrogen deficiency symptoms, whose last menstrual period was more than 12 months ago
- The dosage can be adjusted depending on clinical response and the preparation continued if well tolerated
- Consider using the ultra-low dose Femoston®-conti 0.5mg /2.5mg preparation in women over the age of 60

Consideration for oral therapy



- Personal choice and preference
- Previously taken combined oral contraceptive (COCP)
- Patient adherence: once-daily treatment
- Aesthetics: non-visible
- May be the preferred route for younger menopausal women <45 years

HRT should be individualised to each woman and it is important to counsel women on the benefits and risks of HRT before initiating treatment.[1,3]

The Femoston® range in summary:

- Effectively treats vasomotor symptoms associated with the menopause[4-7]
- Offers a range of sequential and continuous combined treatments with various doses[4-7]
- Contains a highly selective progestogen, dydrogesterone[15] which is used to prevent the excess risk of endometrial hyperplasia and carcinoma from estrogen stimulation[4-7]

femoston® estradiol / dydrogesterone femoston®-conti estradiol / dydrogesterone

HRT: Hormone replacement therapy.

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References

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6. Femoston®-conti 0.5 mg/2.5 mg Summary of Product Characteristics.
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femoston® / femoston®-conti

estradiol / dydrogesterone

PRESCRIBING INFORMATION (combined)

Femoston-conti 0.5 mg/2.5 mg film-coated tablets | **Femoston 1/10 mg film-coated tablets**
Femoston-conti 1 mg/5 mg film-coated tablets | **Femoston 2/10 mg film-coated tablets**

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.

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.

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/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 estrogens 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 the combination drug regimen ombitasvir/paritaprevir/ritonavir with or without dasabuvir and also the regimen with glecaprevir/pibrentasvir. 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 inhibiton 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, astheric 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.

Legal Category: POM **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 **MAH:** Mylan Products Ltd., 20 Station Close, Potters Bar, Herts, EN6 1TL, UK **NHS Price:** Femoston-conti £24.43 (84 tablets) & Femoston £16.16 (84 tablets) **Date of Revision of Prescribing Information:** June 2022 **Veeva Reference:** FEM-2022-0062

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 Viatris Medical Information, Building 4, Trident Place, Hatfield Business Park, Mosquito Way, Hatfield, Hertfordshire, AL10 9UL, phone no. 01707 853000, Email: info.uk@viatris.com.

Please continue to report suspected adverse drug reactions with any medicine or vaccine to the MHRA through the Yellow Card Scheme. It is easiest and quickest to report adverse drug reactions online via the Yellow Card website: https://yellowcard.mhra.gov.uk/ or search for MHRA Yellow Card in the Google Play or Apple App Store. Alternatively, you can report via some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) or by calling the Commission on Human Medicines (CHM) free phone line: 0800-731-6789. Adverse reactions/events should also be reported to MAH at e-mail address: pv.uk@viatris.com.

Elleste™

estradiol +/- norethisterone

PRESCRIBING INFORMATION
ELLESTE™ (estradiol +/- norethisterone acetate)
Please refer to Summary of Product Characteristics (SmPC) before prescribing.

Presentation: Elleste Solo™ 1 mg and 2 mg film-coated tablets containing estradiol hemihydrate 1 mg and 2 mg respectively. Elleste Duet™ 1 mg film-coated tablets containing estradiol hemihydrate 1 mg (white tablets) and estradiol hemihydrate 1 mg and norethisterone acetate 1 mg (pale green tablets). Elleste Duet™ 2 mg film-coated tablets containing estradiol hemihydrate 2 mg (orange tablets) and estradiol hemihydrate 2 mg and norethisterone acetate 1 mg (grey tablets). Elleste Duet Conti film-coated tablets (grey tablets) containing 2 mg estradiol hemihydrate and 1 mg norethisterone acetate.

Indication: Hormone replacement therapy for oestrogen deficiency symptoms in peri- and post-menopausal women (Elleste Solo™; Elleste Duet™) and in post-menopausal women with an intact uterus who are at least one-year post menopause (Elleste Duet™ Conti). Prevention of osteoporosis in post-menopausal women at high risk of future fractures who are intolerant of, or contraindicated for, other medicinal products approved for the prevention of osteoporosis (Elleste Duet™ Conti; Elleste Duet™ 2 mg; Elleste Solo™ 2 mg).

Dosage and administration: Elleste Solo™ 1 mg and 2 mg film-coated tablets: One tablet daily to be taken orally and continuously in hysterectomised women; in women with an intact uterus, progestogen should be added for 12-14 days each cycle. Elleste Duet 1 mg film-coated tablets: One white tablet to be taken daily for 16 days followed by one pale green tablet to be taken daily for the next 12 days, then begin a new cycle without a break. For oral use. Elleste Duet™ 2 mg film-coated tablets: One orange tablet to be taken daily for 16 days followed by one grey tablet to be taken daily for the next 12 days, then begin a new cycle without a break. For oral use. Elleste Duet™ Conti: One grey tablet to be taken daily. For oral use. Please refer SmPC for full details on initiating therapy and switching from other forms of HRT.

Contraindications: Known, past or suspected breast cancer. Known or suspected oestrogen-dependent malignant tumours. Undiagnosed genital bleeding. Untreated endometrial hyperplasia. Previous idiopathic or current venous thromboembolism. Known thrombophilic disorders. Active or recent arterial thromboembolic disease. Acute liver disease or history of liver disease as long as LFTs are abnormal. Hypersensitivity to the active substances or excipients. Porphyria.

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. HRT should only be continued as long as the benefit outweighs the risk. Before initiating or reinstituting HRT, take a complete personal and family medical history and perform appropriate physical examinations. Advise women about what breast changes should be reported. Closely supervise women with the following conditions or a history of them: leiomyoma or endometriosis; history of, or risk factors for, thromboembolic disease; risk factors for oestrogen dependent tumours; hypertension; liver disorders; diabetes mellitus; cholelithiasis; migraine or severe headache; systemic lupus erythematosus; endometrial hyperplasia; epilepsy; asthma; otosclerosis. Discontinue therapy if a contraindication is discovered and in the following conditions: jaundice or deteriorating liver function; significant increase in blood pressure; new onset migraine-type headache; pregnancy; venous thromboembolism (patients should contact their doctor immediately if they develop painful swelling of a leg, sudden pain in the chest, shortness of breath). Risk of endometrial hyperplasia and carcinoma are increased when oestrogens are administered alone for prolonged periods. The risk is reduced with the addition of a progestogen for at least 12 days per cycle in non-hysterectomised women. 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. HRT is associated with an increased relative risk of venous thromboembolism (VTE) or pulmonary embolism (PE). Risk factors include personal or family history of thrombosis, severe obesity, systemic lupus erythematosus, immobilisation, major trauma and major surgery. Consider discontinuing HRT 4-6 weeks before elective surgery requiring immobilisation. Therapy should be discontinued if VTE develops after initiating surgery. There is an increased risk of cardiovascular morbidity during the first year of use of HRT. HRT is associated with an up to 1.5-fold increased risk of stroke. Long term use of oestrogens in women has been associated with an increased risk of ovarian cancer. Oestrogens may cause fluid retention. Women with pre-existing hypertriglyceridemia should be followed closely (risk of pancreatitis). Exogenous estrogens may induce or exacerbate symptoms of hereditary and acquired angioedema. Certain endocrine tests may be affected. No evidence for improvement in cognitive function. Increased risk of gallbladder disease. Liver tumours leading to intra-abdominal haemorrhage have been reported. Patients with rare hereditary disorders of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine. Elleste™ Duet 2 mg film-coated tablets and Elleste™ Solo 2 mg film-coated tablets contain sunset yellow colouring (E110) which can cause allergic reactions. May interact with other medicines. Please refer SmPC for further information.

Interaction with other medicinal products: The metabolism of oestrogens and progestogens may be increased by concomitant use of substances known to induce drug-metabolising enzymes, specifically cytochrome P450, such as anticonvulsants (e.g. phenobarbital, phenytoin, carbamazepine) and anti-infectives (e.g. rifampicin, rifabutin, nevirapine, efavirenz). Ritonavir, telaprevir, nelfinavir and herbal preparations containing St John's Wort may induce the metabolism of oestrogens and progestogens. Caution is warranted for co-administration with the combination drug regimen ombitasvir/paritaprevir/ritonavir with or without dasabuvir and also the regimen glecaprevir/pibrentasvir. Please refer SmPC for further information.

Pregnancy and lactation: 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 side effects (>1/10): Headache, breast pain and tenderness, dysmenorrhoea, menstrual disorder. Common side effects (>1/100): Rash, itching; uterine/vaginal bleeding; breast tenderness and enlargement; increase in size of uterine fibroids; nausea; abdominal pain; headache; weight increase / decrease; oedema; change in mood including anxiety and depressive mood; change in libido. Other side effects include: Vaginal candidiasis; vomiting; gallbladder disease; pancreatitis, gallstones; dizziness; migraine; increased blood pressure; leg cramps; alopecia; hirsutism; venous thromboembolism; thrombophlebitis; thrombosis; endometrial neoplasia; dysmenorrhoea; aggravation of endometriosis; changes in cervical eversion, production of mucus and erosion; cystitis-like syndrome; endometrial cancer; breast cancer; bloating; myocardial infarction; stroke; liver tumours; cholestatic jaundice; chloasma; erythema multiforme; erythema nodosum; muscle cramps; vascular purpura; visual disturbances; intolerance to contact lenses; sodium and water retention; reduced glucose tolerance; and probable dementia. Please refer SmPC for further information.

Legal Category: POM

Marketing Authorisation Numbers and Basic NHS Price: Elleste Solo™ 1mg: PL 46302/0169; 3 x 28 film-coated tablets £5.06. Elleste Solo™ 2mg: PL 46302/0170; 3 x 28 film-coated tablets £5.06. Elleste Duet™ 1mg: PL 46302/0164; 3 x 28 film-coated tablets £9.20. Elleste Duet™ 2mg: PL 46302/0165; 3 x 28 film-coated tablets £9.20. Elleste Duet™ Conti: PL 46302/0166; 3 x 28 film-coated tablets £17.02.

MAH: Mylan Products Ltd. Further information is available on request from: Mylan Products Ltd., Station Close, Potters Bar, Herts, EN6 1LT. Tel. 01707 853000

Date of Last Revision: June 2022

Veeva Reference: ELL-2022-0021

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.uk@viatris.com

Please continue to report suspected adverse drug reactions with any medicine or vaccine to the MHRA through the Yellow Card Scheme. It is easiest and quickest to report adverse drug reactions online via the Yellow Card website: http://yellowcard.mhra.gov.uk/ or search for MHRA Yellow Card in the Google Play or Apple App Store. Alternatively, you can report via some clinical IT systems (EMIS/SystemOne/Vision/MiDatabank) or by calling the Commission on Human Medicines (CHM) free phone line: 0800-731-6789.

Adverse reactions/events should also be reported to MAH at e-mail address: pv.uk@viatris.com