# ELLESTE (estradiol +/- norethisterone acetate)
# PRESCRIBING INFORMATION

**PRESENTATION**: Elleste Solo™ 1 mg and 2 mg film-coated tablets containing estradiol hemihydrate 1 mg and 2 mg respectively. Elleste Solo™ MX 40 mcg transdermal patch containing 1.25 mg estradiol hemihydrate and Elleste Solo™ MX 80 mcg Transdermal Patch containing 2.5 mg estradiol hemihydrate and delivers 40 and 80 micrograms of estradiol respectively per 24 hours. 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 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™; Elleste Solo™ MX 40 patch) 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; Elleste Solo™ MX 80 patch).

**DOSAGE AND ADMINISTRATION**: Elleste Solo™ 1 mg and 2 mg film-coated tablets: One tablet daily in hysterectomised women; in women with an intact uterus, progestogen should be added for 12-14 days each cycle. Elleste Solo™ MX 40 and 80 patch: initiate treatment with Elleste Solo™ MX 40 in women with menopausal symptoms. If menstruating regularly, start within five days of bleeding. See SmPC for details of switching from other forms of HRT. Apply one patch twice weekly; in women with an intact uterus, progestogen should be added for 12-14 days during each cycle. The dosage may be increased by using Elleste Solo™ MX 80. Elleste Duet 1 mg film-coated tablets: One white tablet taken daily for 16 days followed by one pale green tablet taken daily for 12 days, then begin a new cycle without a break. Elleste Duet™ 2 mg film-coated tablets: One orange tablet taken daily for 16 days followed by one grey tablet taken daily for 12 days, then begin a new cycle without a break. Elleste Duet™ Conti: One tablet taken daily.

**CONTRA-INDICATIONS**: Pregnancy or breastfeeding. Known, past or suspected breast cancer. Known or suspected oestrogen-dependent malignant tumours. Undiagnosed genital bleeding. Untreated endometrial hyperplasia. Active thrombophlebitis. 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. Dubin-Johnson or Rotor Syndromes. Hypersensitivity to the active substances or excipients. Porphyria.

**WARNINGS 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: hepatitis, jaundice or deteriorating liver function; significant increase in blood pressure; sudden severe chest pain; sudden breathlessness; unexplained swelling or pain in calf; severe stomach pain; prolonged immobility after surgery or leg injury; new onset migraine-type headache; pregnancy. 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 hysterectomised 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). 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. See SmPC for potential interactions.

**SIDE EFFECTS**: Common side effects (>1/100): Erythema, itching; uterine 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; rash; itching; 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; steepening of corneal curvature; visual disturbances; intolerance to contact lenses; sodium and water retention; reduced glucose tolerance; aggravation of porphyria and probable dementia. See SmPC for all side effects.

**MARKETING AUTHORISATION NUMBERS AND COST**: Elleste Solo™ 1 mg: PL15142/0061; 3 x 28 film-coated tablets £5.06. Elleste Solo™ 2 mg: PL15142/0062; 3 x 28 film-coated tablets £5.06. Elleste Solo™ MX 40 mcg: PL15142/0060; 8 patches £5.19. Elleste Solo™ MX 80 mcg: PL15142/0059; 8 patches £5.99. Elleste Duet™ 1 mg: PL15142/0063; 3 x 28 film-coated tablets £9.20. Elleste Duet™ 2 mg: PL15142/0064; 3 x 28 film-coated tablets £9.20. Elleste Duet™ Conti: PL15142/0065; 3 x 28 film-coated tablets £17.02.

**MARKETING AUTHORISATION HOLDER**: Meda Pharmaceuticals Ltd. Further information is available on request from: Meda Pharmaceuticals Ltd., Skyway House, Parsonage Road, Takeley, Bishop's Stortford CM22 6PU. Tel. 0845 4600000. Date of preparation: November 2015. UK/ELL/14/0003(1)

**Adverse events should be reported.**
**Reporting forms and information can be found at www.mhra.gov.uk/yellowcard.**
**Adverse events should also be reported to Meda's Medical Information line on 01748 828810.**