

PRESCRIBING INFORMATION

Estradiol 10 micrograms vaginal tablets (estradiol hemihydrate)

Presentation: Vaginal tablet contains estradiol hemihydrate equivalent to estradiol 10mcg.

Indications: Treatment of vaginal atrophy due to oestrogen deficiency in postmenopausal women. The experience treating women older than 65 years is limited.

Dosage and administration: Intravaginally as a local oestrogen therapy by use of an applicator. *Initial dose:* One vaginal tablet daily for two weeks. *Maintenance dose:* One vaginal tablet twice a week. For initiation and continuation of treatment of postmenopausal symptoms, the lowest effective dose for the shortest duration should be used.

Contraindications: Known, past or suspected breast cancer, and oestrogen-dependent malignant tumours (e.g. endometrial cancer), Undiagnosed genital bleeding, untreated endometrial hyperplasia, previous or current venous thromboembolism (deep venous thrombosis, pulmonary embolism), known thrombophilic disorders (e.g. protein C, protein S, or antithrombin deficiency), active or recent arterial thromboembolic disease (e.g. angina, myocardial infarction), acute liver disease, or a history of liver disease as long as liver function tests have failed to return to normal, known hypersensitivity to the active substances or to any of the excipients, porphyria.

Precautions and warnings: 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. Leiomyoma (uterine fibroids) or endometriosis, risk factors for thromboembolic disorders, risk factors for oestrogen-dependent tumours, e.g. 1st degree heredity for breast cancer, hypertension, liver disorders (e.g. liver adenoma), diabetes mellitus with or without vascular involvement, cholelithiasis, migraine or (severe) headache, systemic lupus erythematosus, a history of endometrial hyperplasia, epilepsy, asthma, otosclerosis may recur or be aggravated during oestrogen treatment. Therapy should be discontinued in case a contraindication for jaundice or deterioration in liver function, significant increase in blood pressure, new onset of migraine-type headache, pregnancy. Repeated treatment should be reviewed at least annually, with special consideration given to any symptoms of endometrial hyperplasia or carcinoma. Caution is advised when using this product in women who have undergone hysterectomy because of endometriosis, especially if they are known to have residual endometriosis. Increased risk of ovarian cancer, venous thromboembolism, ischaemic stroke must be considered in case of long term or repeated use. Oestrogens may cause fluid retention, and therefore patients with cardiac or renal dysfunction should be carefully observed. Women with preexisting hypertriglyceridaemia and increased thyroid binding globulin should be followed closely during oestrogen replacement or HRT. Intravaginal applicator may cause minor local trauma, especially in women with serious vaginal atrophy.

Interactions: Due to the vaginal administration and minimal systemic absorption, it is unlikely that any clinically relevant drug interactions will occur with Estradiol. However, interactions with other locally applied vaginal treatments should be considered.

Pregnancy and lactation: Estradiol is not indicated during pregnancy and lactation.

Undesirable effects: *Serious:* breast cancer, endometrial cancer, generalised hypersensitivity reactions (e.g. anaphylactic reaction/shock), urticaria, rash erythematous, rash pruritic, genital pruritus, With systemic HRT use - ovarian cancer, venous thromboembolism, ischaemic stroke. *Common:* Headache, abdominal pain, nausea, vaginal haemorrhage, vaginal discharge or vaginal discomfort.

(Please refer to the Summary of Product Characteristics for detailed information)

Overdose: Estradiol is intended for intravaginal use and the dose of estradiol is very low. Overdose is therefore unlikely, but if it occurs, treatment is symptomatic.

Legal Category: POM.

Basic NHS Price: £15 per pack of 24 tablets.

Marketing authorisation number: PL PL 12762/0619

Marketing authorisation holder: Mercury Pharmaceuticals Ltd Dashwood House, 69 Old Broad Street, London, EC2M 1QS, United Kingdom.

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Adverse events should be reported. Reporting forms and information can be found at <https://yellowcard.mhra.gov.uk/> Adverse events should also be reported to **Advanz Pharma** Medical Information via telephone on +44 (0) 208 588 9131 via e-mail at medicalinformation@advanzpharma.com