OVESTIN 1 mg CREAM

Presentation: Cream for intravaginal use, 1mg estriol in 1g cream

Uses: Hormone replacement therapy for treatment of atrophic vaginitis (due to oestrogen deficiency) in peri- and post-menopausal women. As pre-surgery therapy for vaginal operations and during subsequent convalescence.

Dosage and Administration: Atrophic vaginitis: For initiation and continuation of treatment of postmenopausal symptoms, the lowest effective dose for the shortest duration should be used. Usual dose is one applicator-dose (0.5g cream containing 0.5mg estriol) per day for 2 to 3 weeks. As maintenance dosage, one applicator-dose twice a week. Pre-surgery therapy: One applicator-dose per day should begin 2 weeks before the operation.

Following surgery: a period of at least 2 weeks should be allowed before resuming therapy using one applicator-dose twice a week. Ovestin Cream may be started on any day in women not taking HRT or switching from another continuous combined HRT product. In women switching from a cyclic HRT product, Ovestin Cream should be started one week after completion of the cycle. Cyclic administration of a progestogen is not necessary provided the daily dose does not exceed one applicator-dose and this maximum dose is not used for more than several weeks. Contraindications: Pregnancy or breast-feeding; known past or suspected breast cancer; known or suspected oestrogen-dependent malignant tumours; undiagnosed genital bleeding; untreated endometrial hyperplasia; previous or current venous thromboembolism; known thrombophilic disorders (e.g. protein C, protein S, or antithrombin deficiency); active or recent arterial thromboembolic disease; acute liver disease, or history of liver disease as long as liver function tests have failed to return to normal; hypersensitivity to any of the constituents of Ovestin 1 mg Cream; porphyria. Precautions and warnings: HRT should only be initiated for symptoms that adversely affect quality of life. An appraisal of the risks and benefits should be undertaken at least annually. A full medical history should be taken before treatment. Existing vaginal infections should be treated before therapy with Ovestin cream is started. Patients with some medical conditions including, leiomyoma or endometriosis, a history of or risk factors for thromboembolic disorders, hypertension, liver disorders, diabetes mellitus with or without vascular involvement, cholelithiasis, migraine or (severe) headache, systemic lupus erythematosus, a history of endometrial hyperplasia, epilepsy, asthma and otosclerosis, will need close supervision particularly when the condition is active, or has occurred previously and/or was aggravated during pregnancy or previous hormone treatment - see SPC for full details. These conditions may recur or be aggravated during treatment with Ovestin cream. Discontinue treatment if contraindicated, jaundice or a deterioration in liver function occurs, there is a significant increase in blood pressure, a new onset of migraine or pregnancy occurs. If breakthrough bleeding or spotting occurs, the reason should be investigated. For full details on the warnings associated with HRT and endometrial safety, breast cancer, VTE, coronary artery disease, stroke and ovarian cancer, refer to SPC. Patients with cardiac or renal dysfunction or hypertri-glyceridemia should be carefully observed. Interactions: None reported in clinical practice but an increased metabolism of oestrogens may occur with substances known to induce cytochrome P450 enzymes such as anticonvulsants, anti-infectives and St John’s wort. Estriol may increase the pharmacological effects of corticosteroids, succinylcholine, theophyllines and troleandomycin. Undesirable effects: The following reactions associated with oestrogen therapy may occur with estriol therapy or overdose: nausea and vomiting, breast tenderness or pain in the breasts, vaginal bleeding or spotting during or on withdrawal of therapy, excessive production of cervical mucus, headache, application site irritation and pruritus. These adverse reactions are usually transient, but may also be indicative of too high a dosage. An up to 2-fold increased risk of having breast cancer diagnosed is reported in women taking combined oestrogen-progestogen therapy for more than 5 years. Any increased risk in users of oestrogen-only therapy is substantially lower than seen in users of oestrogen-progestogen combinations. The level of risk is dependent on duration of use. Long-term use of oestrogen-only and combined oestrogen-progestogen HRT has been linked with a slightly increased risk of ovarian cancer. HRT is associated with a 1.3-3-fold increased relative risk of developing venous thromboembolism. The occurrence of such an event is more likely in the first year of use. Oestrogen-only and oestrogen-progestogen therapy is associated with an up to 1.5 fold increased relative risk of ischaemic stroke, independent of age or duration of use but the baseline risk is age-dependent. After age 60, a slightly increased risk of coronary artery disease is reported for combined oestrogen-progestogen HRT. Other reactions reported with oestrogen-only and oestrogen-progestogen combined treatment: oestrogen-dependent neoplasms, gall bladder disease, choiasma, erythema multiforme, erythema nodosum, vascular purpura, probable dementia over the age of 65. Overdose: The acute toxicity of estriol in animals is very low. Symptoms of acute oral overdose are nausea, vomiting and withdrawal bleeding in females. No specific antidote is known. If necessary a symptomatic treatment should be given.
Please refer to the full SPC text before prescribing this product. Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard (UK). Adverse events should also be reported to MSD (tel: 01992-467272).

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