Prescribing Information

Imvaggis (Estriol) 0.03 mg pessary

For full prescribing information, including side effects, precautions and contraindications, please consult the Summary of Product Characteristics (SPC).

Presentation: Pessaries containing 0.03 mg of estriol. **Indication:** Local treatment of vaginal symptoms of estrogen deficiency in postmenopausal women. **Dosage and Administration**: During the first 3 weeks of treatment, 1 pessary is administered daily. Thereafter, a maintenance dose of 1 pessary twice a week is recommended. The pessary should be introduced deeply into the vagina, preferably in the evening before going to bed. For initiation and continuation of treatment, the lowest effective dose for the shortest duration should be used. For full details of usage please refer to the SPC. **Contraindications:** Hypersensitivity to estriol or any of the excipients; known, past or suspected breast cancer; known or suspected estrogen-dependent malignant tumours (e.g. endometrial cancer); undiagnosed genital bleeding; untreated endometrial hyperplasia; previous or current venous thromboembolism (deep vein thrombosis, pulmonary embolism), known thrombophilic disorders, active or recent arterial thromboembolic disease (e.g. angina, myocardial infarction); acute liver disease or history of liver disease whilst liver function tests are abnormal; porphyria**. Warnings and Precautions:** Local estrogen therapy should only be initiated for symptoms that adversely affect quality of life. The risks and benefits should be reviewed annually, and therapy should only be continued as long as the benefit outweighs the risk. Estriol must not be combined with estrogen preparations for systemic treatment. A personal and family medical history should be taken before initiating or reinstituting estriol treatment. Periodic check-ups are recommended during treatment. Frequency and nature of the examinations should be adapted to the individual risks of the woman. Investigations, including mammography are recommended according with current screening practices. Patients should be closely supervised if any of the following conditions are present, have occurred previously and/or have been aggravated during pregnancy or previous hormone treatment since they may recur or be aggravated during treatment with Estriol: leiomyoma (uterine fibroids) or endometriosis; risk factors for thromboembolic disorders; risk factors for estrogen-dependent tumours; hypertension; liver disorders; diabetes mellitus with or without vascular involvement; cholelithiasis; migraine or severe headache; systemic lupus erythematosus; history of endometrial hyperplasia; epilepsy; asthma and otosclerosis. Estriol should be discontinued if a contraindication is discovered or the following occur: jaundice or deterioration in liver function; significant increase in blood pressure; new onset of migraine-type headache; pregnancy. An increased risk of endometrial hyperplasia or uterine cancer has not been attributed to treatment with estriol by vaginal use. Endometrial safety of long-term (>1 year) or repeated use of local vaginally administered estrogen is uncertain. Therefore, if repeated, treatment should be reviewed at least annually. If break through bleeding and spotting occurs during therapy or continues after treatment has been discontinued the reason should be investigated. Unopposed estrogen stimulation may lead to premalignant transformation in the residual foci of endometriosis. The following risks have been associated with systemic HRT and apply to a lesser extent to estrogen products for vaginal application where systemic exposure is very low, however they should be considered in case of long term or repeated use: Breast cancer, ovarian cancer, venous thromboembolism, coronary artery disease, ischaemic stroke, and certain other conditions including fluid retention. Therefore, patients with cardiac or renal dysfunction should be carefully observed. Please refer to the SPC for full details. **Interactions:** No clinically relevant interactions with other medicinal products are expected following vaginal administration of low-dose estriol pessaries. If estriol pessaries are used simultaneously with condoms made of latex, it can decrease the tensile strength and thus impair the safety of condoms. **Pregnancy and breastfeeding:** Estriol pessaries are not indicated in pregnancy or during breastfeeding. If pregnancy occurs during treatment with Estriol pessaries, the treatment should be withdrawn immediately. **Undesirable effects:** At the beginning of treatment, when the vaginal epithelial layers are still atrophic, local irritation may occur as a sensation of heat, pain and/or itching. They are often transient and of mild intensity. The following commonly (>1/100; <1/10) occur: vulvovaginal burning, pruritus, pain and dysuria. The following are uncommon (≥1/1,000; <1/100): vaginal discharge, anorectal discomfort. For further information on side effects and risk estimates, please consult the SPC. **Overdose:** Toxicity for estriol is very low. Overdose of Estriol pessaries by vaginal application is unlikely. Symptoms that may occur in the case of a high dose accidentally ingested are nausea, vomiting and vaginal bleeding in females. **NHS Price:** 24 pessaries, £13.38. **Legal category:** POM. **Marketing Authorisation number:** PL 42714/0001. **Marketing Authorisation Holder:** Besins Healthcare (UK) Ltd, 1st Floor, 28 Poland Street, London, W1F 8QN, UK. **Date of preparation of Prescribing Information:** September 2019. BHUK/2019/168

Adverse events 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 also be reported to Besins Healthcare (UK) Ltd, Drug Safety on 0203 862 0920 Email: pharmacovigilance@besins-healthcare.com

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