Gynest® (estriol) 0.01 % w/w vaginal cream Prescribing Information

Please consult the full summary of product characteristics (SmPC) before prescribing

Presentation: Gynest vaginal cream contains estriol 0.01 % w/w.

Indications: *Hormone replacement therapy* for treatment of atrophic vaginitis and kraurosis in postmenopausal women. Treatment of *pruritus vulvae* and *dyspareunia* associated with atrophic vaginal epithelium.

Dosage and administration: *Initiation and continuation of treatment of postmenopausal symptoms:* lowest effective dose for the shortest duration should be used. Attempts to discontinue medication should be made at three to six month intervals following physical examination. *Atrophic vaginitis or associated symptoms (e.g. dyspareunia, pruritus) initial daily dose:* one applicator full per day. *Maintenance dose:* one applicator full twice a week may be used after restoration of the vaginal mucosa has been achieved. Gynest cream is for intravaginal use, using a filled applicator. This should be inserted high into the vagina and emptied, preferably in the evening.

Contraindications: Hypersensitivity to estriol or any of the excipients. Known, past or suspected cancer of the breast or estrogen-dependent malignant tumours (e.g. endometrial cancer); undiagnosed genital bleeding; untreated endometrial hyperplasia; previous or current venous thromboembolism; known thrombophilic disorders; active or recent arterial thromboembolic disease; acute liver disease, or a history of liver disease as long as liver function tests have failed to return to normal; porphyria.

Precautions and warnings: For the treatment of postmenopausal symptoms, 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. Gynest Cream contains arachis oil (peanut oil) and should not be applied by patients known to be allergic to peanuts and also avoided by patients with soya allergy. Before initiating or reinstituting HRT a complete medical history should be taken and women advised of recommended periodic checkups and changes in breasts which should be reported. Close supervision is recommended if any of the following conditions are present (and/or been aggravated in pregnancy); leiomyoma; thromboembolic disorder risk factors; estrogen dependent tumour risk factors (e.g. breast cancer, endometrial carcinoma, ovarian cancer); hypertension; liver disorders; diabetes mellitus; cholelithiasis; migraine or (severe) headache; systemic lupus erythematous; history of endometrial hyperplasia; epilepsy; asthma; otosclerosis. Patients should also be closely observed if cardiac or renal disfunction is present, due to potential fluid retention; and in patients with pre-existing hypertriglyceridaemia due to rare cases of large increases in triglycerides leading to pancreatitis. Transvaginal estrogens may affect protein binding (e.g. thyroid binding globulin, corticosteroids and sex hormones) produced by the liver less than oral hormones. Treatment should be immediately withdrawn if a contraindication is discovered or in the case of jaundice/liver function deterioration; significant increase in blood pressure; new onset migraine-type headache or pregnancy. Contact between contraceptive diaphragms or condoms to be avoided since the rubber may be damaged by the cream.

For further information on special warnings, precautions and interactions please refer to SmPC.

Pregnancy and lactation: Gynest cream not indicated in pregnancy or lactation, withdraw therapy if pregnancy occurs.

Undesirable effects: Breast pain, micturition frequency increased, vaginal discharge, cystitis, leg pain, pre-menstrual tension, lower abdominal pain, palpitations and depression have been reported in a placebo controlled trial with Gynest. Other AEs reported with estrogen/progestogen treatment are gall bladder disease; skin and subcutaneous tissue disorders and probable dementia over age 65. *Serious adverse events* reported with estrogen therapy include; breast cancer; endometrial cancer; ovarian cancer; venous thromboembolism; coronary artery disease and ischaemic stroke. **Please refer to SmPC for full details, including relative risk data from large studies.**

Legal Category: POM

Presentation and cost: 80 g plus applicator £24.98

Marketing authorisation holder and numbers: Marlborough Pharmaceuticals Ltd. 35A High Street, Marlborough SN8 1LW, UK. PL 23138/0012

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Further information available from: Marlborough Pharmaceuticals Ltd., Sovereign House, Miles Gray Road, Basildon, Essex, SS14 3FR, UK.

Adverse events should be reported. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme 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 Marlborough Pharmaceuticals Ltd. on +44 (0) 1279 406759 or by email to atnahspv@diamondpharmaservices.com