Prescribing information: BLISSEL® (ESTRIOL 50 micrograms/1g) VAGINAL GEL

PRESCRIBING INFORMATION: Please refer to Summary of Product Characteristics (SmPC) before prescribing.
ACTIVE INGREDIENT: 1g vaginal gel contains 50 micrograms estriol.
INDICATIONS: Treatment of symptoms of vaginal atrophy due to estrogen deficiency in postmenopausal women.
DOSAGE AND ADMINISTRATION: Use the lowest effective dose for the shortest duration. **Treatment initiation or reinstitution:** One applicator-dose per day for 3 weeks at bedtime. Only initiate local estrogen therapy for symptoms that adversely affect quality of life. Take a complete personal and family medical history. Use this, and the contraindications and warnings for use, to guide physical (including pelvic and breast) examination. Treat vaginal infections before starting therapy. **Maintenance treatment:** One applicator-dose twice weekly emptied into vagina at bedtime. **Evaluation:** Evaluate treatment continuation after 12 weeks. Conduct periodic check-ups and investigations, adapted to the individual, including mammography, in accordance with accepted screening practices. Advise of breast changes that should be reported. Appraise the risks and benefits at least annually and continue only if the benefit outweighs the risk. Administer a missed dose as soon as remembered. Skip doses 12 hours or more overdue and administer the next dose at the normal time. **Administration:** Empty dose-marked applicator into vagina in accordance with instructions in the information leaflet.
CONTRAINDICATIONS: Known, past or suspected breast cancer, known or suspected estrogen-dependent malignant tumour, undiagnosed genital bleeding, untreated endometrial hyperplasia, previous idiopathic or current venous thromboembolism, active or recent arterial thromboembolic disease, known thrombophilic disorders, acute liver disease or a history of liver disease as long as liver function tests have failed to return to normal, porphyria, hypersensitivity to the active substance or to any of the excipients. Discontinue immediately if a contraindication is discovered and in cases of jaundice or deterioration in liver function, significant increase in blood pressure, new onset of migraine-type headache or pregnancy.
SPECIAL WARNINGS AND PRECAUTIONS: Do not combine with estrogen preparations for systemic treatment. Intravaginal applicator may cause minor local trauma, especially in women with serious vaginal atrophy. Excipients may cause allergic reactions (possibly delayed). Close supervision of patients with current, previous, or where the condition has been aggravated during pregnancy, or previous hormone treatment: Leiomyoma or endometriosis, risk factors for thromboembolic disorders or 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, otosclerosis. Addition of a progestogen is not recommended. Endometrial safety of long-term (> one year), or repeated use of, vaginal oestrogen is uncertain so treatment should be reviewed at least annually. Investigate breakthrough bleeding or spotting occurring at any time on therapy to exclude endometrial malignancy. Caution in women who have undergone hysterectomy because of endometriosis, especially if there is residual endometriosis. Risks associated with systemic HRT apply to a lesser extent for vaginally applied oestrogens but they should be considered in case of long term or repeated use. Epidemiological evidence from a large meta-analysis suggests no increase in risk of breast cancer in women with no history of breast cancer taking low dose vaginally applied oestrogens. It is unknown if low dose vaginal oestrogens stimulate recurrence of breast cancer. Increased risk of ovarian cancer, venous thromboembolism (VTE), coronary artery disease and ischaemic stroke associated with systemic HRT.
Generally recognised risk factors for VTE include use of estrogens, older age, major surgery, prolonged immobilisation, obesity (BMI > 30 kg/m2), pregnancy/ postpartum period, systemic lupus erythematosus and cancer. No consensus about the possible role of varicose veins in VTE. Estrogens with systemic effects may cause fluid retention or increase of plasma triglycerides. Therefore, careful observation of patients with heart diseases or impaired renal function or with pre-existing hypertriglyceridemia during the first weeks of treatment is recommended. No systemic effects expected with Blissel low dose estriol vaginal gel. Careful observation in severe renal insufficiency as levels of circulating estriol may be increased.
INTERACTIONS: No interaction studies have been performed. Due to vaginal administration, and minimal systemic absorption, no clinically relevant interactions are expected. Consider interactions with other locally applied vaginal treatments.
FERTILITY, PREGNANCY, LACTATION: No fertility data available. Not indicated during pregnancy. Withdraw treatment immediately if pregnancy occurs. No data available on exposed pregnancies. Not indicated during lactation.
DRIVING: No influence on ability to drive and use machines.
UNDESIRABLE EFFECTS: Very common: None. **Common**: Pruritus genital, application site pruritus, pruritus. Consult SmPC in relation to less common side effects and class effects associated with systemic HRT.
PHARMACEUTICAL PRECAUTIONS: Store below 25°C.
LEGAL CATEGORY: POM.

Product	Blissel®
Net Wholesale Price	€16.50
Pack Size	30g
Marketing Authorisation Number	PA2102/001/001

MARKETING AUTHORISATION HOLDER: Italfarmaco S.A., San Rafael 3, 28108 Alcobendas (Madrid), Spain. Marketed and distributed in Ireland by Consilient Health (Ireland) Ltd, Block 2A Richview Office Park, Clonskeagh, Dublin 14, D14 Y045. E-mail: irishoffice@consilienthealth.com.

Adverse events should be reported. Reporting forms and information can be found at http://www.hpra.ie/homepage/medicines/safety-information/reporting-suspected-side-effects. Adverse events should also be reported to Consilient Health (Ireland) Ltd, Block 2A Richview Office Park, Clonskeagh, Dublin 14, D14 Y045 or drugsafety@consilienthealth.com

Information about this product, including adverse reactions, precautions, contraindications, and method of use can be found at https://www.hpra.ie/img/uploaded/swedocuments/Licence_PA2102-001-001_09082022145537.pdf IE-BLS-158(3)) Date of Preparation October 2024

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