Blissel®

ESTRIOL 50 micrograms/g VAGINAL GEL

When did you last discuss your patient's vaginal estrogen treatment?

A drop of bliss

The only strongly hydrating mucoadhesive, clear aqueous gel for the local treatment of vaginal atrophy [1,2]

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Blissel Case study

Jane, 56 year old postmenopausal woman

Dx: vulvovaginal atrophy (VVA)

Tx history:
Started on estradiol vaginal tablets but found these uncomfortable
Subsequently prescribed estriol cream

Presentation:
Jane reports a return of her VVA symptoms-burning, irritation, dyspareunia and dysuria

She is tearful in describing the impact on sexual satisfaction and spontaneity and her ability to be intimate with her husband

Jane mentions that because she finds the vaginal cream messy, and often experiences leakage, she uses it only infrequently

She does not report or complain of symptoms that might justify systemic therapy

Patient Satisfaction & Treatment Adherence

Patient acceptability and **preference are** important aspects of local estrogen therapy which is likely to be a **long-term treatment** [3]

Patients often consider **pessaries and creams unhygienic** and both forms are associated with leakage, often necessitating the use of some form of sanitary protection [3]

Adherence guidelines advocate a non-judgemental discussion in which the patients' perceptions and preferences are explored [4]

Have That Discussion

Despite the fact that menopause-related genitourinary symptoms affect up to **50%** of midlife and older women [5] only **10%** of healthcare professionals initiate a discussion on vulvar vaginal atrophy [6]

Patients are often unwilling or embarrassed to report symptoms to their healthcare professional [6]

Advise women offered vaginal estrogen to continue treatment to maintain benefits and that adverse effects are very rare [7]

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88% of women expressed a **positive opinion** for cleanliness, leakage, ease of administration which may improve compliance [8]

Acceptability rated as excellent or good in 74% of women [8]

Improves **Quality of Life** and **Sexual Health** in postmenopausal women [9]

Blissel Case study

Jane, 56 year old postmenopausal woman

RESULT

Jane was Px Blissel: Maintenance dose/dose for patients switching from another vaginal estrogen is 1 application twice weekly for as long as symptoms persist

Jane was advised to continue treatment to maintain benefits and advised that side effects normally associated with systemic oestrogens are very unlikely with intravaginal preparations such as Blissel

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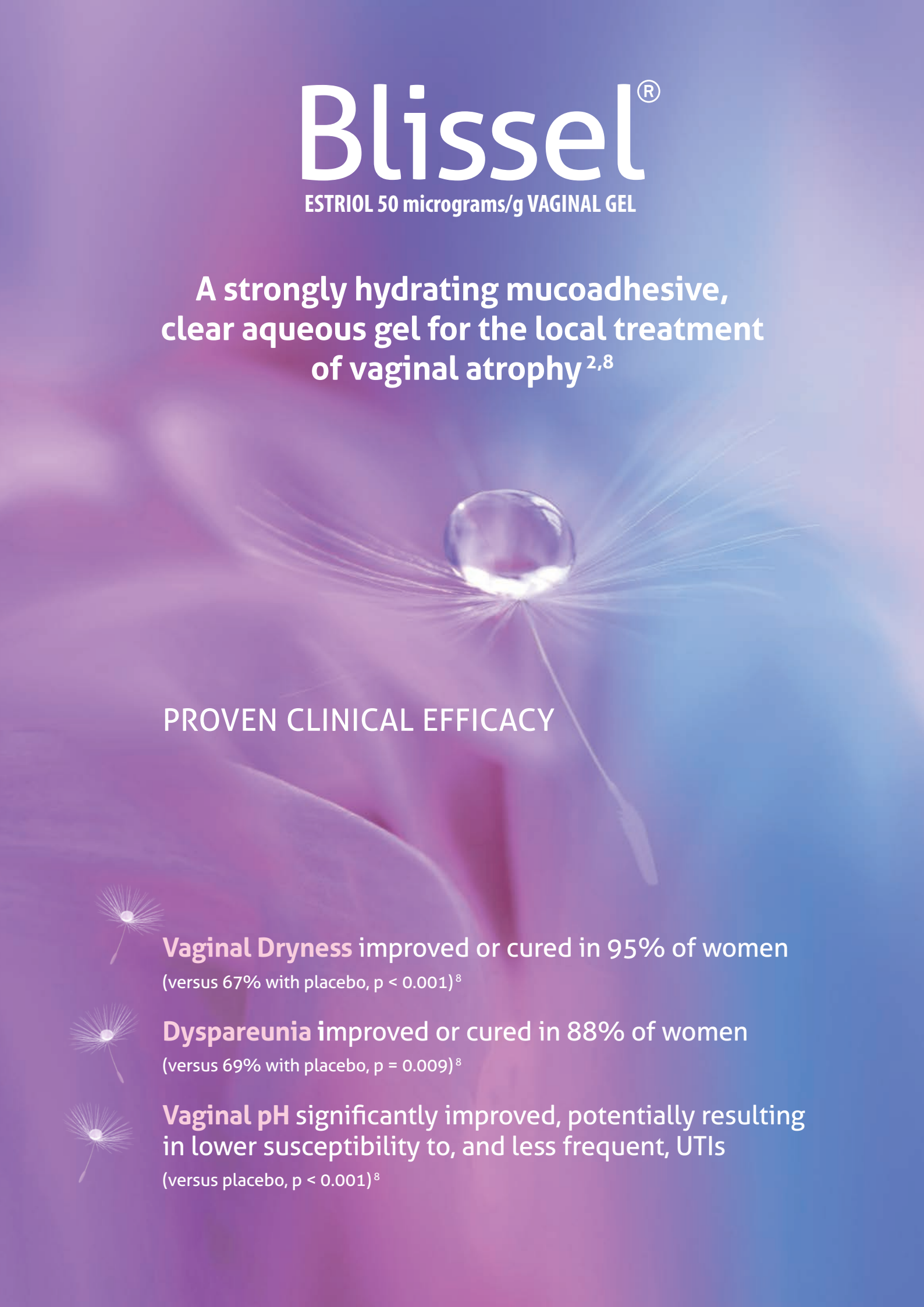
A strongly hydrating mucoadhesive, clear aqueous gel for the local treatment of vaginal atrophy [2,8]



PROVEN CLINICAL EFFICACY

Vaginal Dryness improved or cured in 95% of women
(versus 67% with placebo, $p < 0.001$) [8]

Dyspareunia improved or cured in 88% of women
(versus 69% with placebo, $p = 0.009$) [8]

Vaginal pH significantly improved, potentially resulting in lower susceptibility to, and less frequent, UTIs
(versus placebo, $p < 0.001$) [8]

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References:

1. British National Formulary 79. March – September 2020 **2.** Blissel SmPC, April 2019 (Accessed May 2020) https://www.medicines.org.uk/emc/product/10400 **3.** Dugal R. et al., Acta Obstet Gynecol Scand 2000; 79: 293–297 **4.** North American Menopause Society. 2017: 24 **5.** Portman D. J North American Menopause Soc. 2014;214 **6.** Nappi R.E et al. Climacteric. 2016; 19(2): 188–1977. **7.** NICE guideline [NG 23] 2015 (Last updated December 2019) **8.** Cano A. et al. Menopause, Vol. 19, No. 10, 2012 **9.** Caruso S. J North American Menopause Soc. 2015;23

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:** Local treatment of vaginal dryness in postmenopausal women with vaginal atrophy. **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 at bedtime. 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:** Apply into vagina using dose-marked applicator 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. **SPECIAL WARNINGS AND PRECAUTIONS**: Do not combine with estrogen preparations for systemic treatment. Risk of endometrial hyperplasia and carcinoma in oral treatment solely with estrogen is dependent on treatment duration and estrogen dose. Increased risk of endometrial hyperplasia or uterine cancer has not been attributed to treatment with estriol by vaginal use; if continued treatment is required periodic revisions are recommended, with special consideration to symptoms suggestive of endometrial hyperplasia or endometrial malignancy. 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. Increased risk of certain types of cancer (in particular uterine, ovarian and breast cancer),venous thromboembolism, stroke and coronary artery disease associated with systemic hormone replacement treatment. Blissel vaginal gel administered locally is not expected to increase the risk of cancer, VTE, stroke and coronary artery disease. Generally recognised risk factors for VTE include a personal history or family history, severe obesity (BMI > 30 kg/m^2) and systemic lupus erythematosus . No consensus about the possible role of varicose veins in VTE. Close supervision is recommended in these patients. 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 local treatment using a low dose estriol vaginal gel. Careful observation in severe renal insufficiency as levels of circulating estriol may be increased. 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. Intravaginal applicator may cause minor local trauma, especially in women with serious vaginal atrophy. 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. **INTERACTIONS:** No interaction studies have been performed. No clinically relevant interactions expected. **FERTILITY, PREGNANCY, LACTATION:** 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. **PHARMACEUTICAL PRECAUTIONS:** Store below 25°C. **LEGAL CATEGORY:** POM.

Product	NHS List Price	Pack Size	Marketing Authorisation Number
Blissel	£ 18.90	30g	PL 20663/0003

MARKETING AUTHORISATION HOLDER: Italfarmaco S.A., San Rafael 3, 28108 Alcobendas (Madrid), Spain. Marketed in the UK by Flynn Pharma Limited, Hertlands House, Primett Road, Stevenage, Herts, SG1 3EE, Tel: 01438 727822, E-mail: medinfo@flynnpharma.com.

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 Flynn Pharma Ltd. Medical Information: Tel 01438 727822, E-mail medinfo@flynnpharma.com.

Information about this product, including adverse reactions, precautions, contraindications and method of use can be found at http://www.medicines.org.uk/emc/. **DATE OF REVISION OF PRESCRIBING INFORMATION:** May 2019.

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UK/BLS/2020/947 (v2.0) Date of preparation July 2020