Prescribing Information

Oestrogel (estradiol) Pump-Pack 750 micrograms/actuation
For full prescribing information, including side effects, precautions and contraindications, please consult the Summary of Product Characteristics (SPC).

Presentation: Transdermal gel containing estradiol 0.06% w/w. Each pump actuation is 1.25 g of Oestrogel, which contains 0.75mg of estradiol. Each pump actuation of gel contains 0.5 g of ethanol. **Indication:** 1: Hormone Replacement Therapy (HRT) for oestrogen deficiency symptoms in postmenopausal women. 2: Prevention of osteoporosis in postmenopausal women at high risk of future fractures who are intolerant of, or contraindicated for, other medicinal products approved for the prevention of osteoporosis. The experience treating women older than 65 years is limited. **Dosage and Administration**: Oestrogel is administered once daily, either as a monotherapy or as a continuous sequential treatment (when combined with a progestogen). *Dosing in women without a uterus*: Oestrogel should be administered daily on a continuous basis. It is not recommended to add a progestogen in hysterectomised women, unless there is a previous diagnosis of endometriosis. *Dosing in women with an intact uterus:* In women with an intact uterus, Oestrogel should be combined with a progestagen approved for addition to oestrogen treatment in a continuous sequential dosing scheme. Oestrogel should be administered daily on a continuous basis, the progestagen is added for at least 12 to 14 days (or more) of every 28-day cycle, in a sequential manner to reduce the risk of endometrial hyperplasia and carcinoma. *Menopausal and postmenopausal symptoms*: each metered dose (1 pump actuation) from the dispenser is 1.25 g of Oestrogel. Two pumps (2.5 g) of Oestrogel once daily (1.5 mg estradiol) is the usual starting dose, which in the majority of women will provide effective relief of symptoms. If after one month's treatment effective relief is not obtained, the dosage may be increased accordingly to a maximum of four pumps (5 g) of Oestrogel daily (3.0 mg estradiol). For initiation and continuation of treatment of postmenopausal symptoms, the lowest effective dose for the shortest duration should be used. Initiation of treatment: women who have never taken HRT and are post-menopausal or have very infrequent menstrual cycles: treatment with Oestrogel can be started on any day. Switching from a continuous oestrogen-progestogen combined HRT: treatment with Oestrogel can be started on any day of the cycle. Switching from a cyclic or continuous sequential HRT treatment: finish the therapeutic sequence before beginning treatment with Oestrogel. *Postmenopausal osteoporosis:* The lowest effective dose for the prevention of osteoporosis is not known.

Method of administration : For Local cutaneous use. Before using a new pump pack, it will require priming; the first dose of gel dispensed should be discarded The patient should apply the gel herself. The gel dose should be dispensed and applied to clean, dry, intact areas of skin e.g. on the arms and shoulders, or inner thighs. A thin layer of the gel should be applied to the entire arm on the inside and outside from wrist to shoulder or inner thigh. The area of application should be as large as possible. Oestrogel should NOT be applied on or near the breasts or on the vulval region. A frequent change in application sites is recommended. Oestrogel must be allowed to dry for 5 minutes before covering the skin with clothing. Forgetting a dose may increase the likelihood of break-through bleeding and spotting. Patients should be advised not to apply two doses at the same time. Avoid skin contact with others, particularly a male partner, for at least 1 hour after application. Transfer risk: Secondary exposure to estradiol can potentially occur as a result of passive transfer following skin-to-skin contact. Patients should be informed that others, especially children, should not come in contact with the area of the body where Oestrogel was applied on.

Elderly people: as for adults. The experience treating women older than 65 years is limited. Paediatric population: Oestrogel is not indicated for use in the paediatric population. For full details of usage please refer to the SPC. **Contraindications:** Known hypersensitivity to estradiol or any of the excipients; known, past or suspected breast cancer; known or suspected oestrogen-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:** This medicine is for external use only and should not therefore be swallowed. Care should be taken to ensure cleanliness of the skin and hands during application. Do not apply to damaged skin.
HRT should only be initiated for symptoms that adversely affect quality of life. The risks and benefits should be reviewed annually and HRT only continued as long as the benefit outweighs the risk. A personal and family medical history should be taken before initiating or reinstituting HRT. Periodic check-ups are recommended during treatment. Physical examination and investigations including appropriate imaging tools should be carried out according to the clinical needs of the patient. 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 Oestrogel, in particular: leiomyoma (uterine fibroids) or endometriosis; risk factors for thromboembolic disorders; risk factors for oestrogen-dependent tumours e.g. 1st degree heredity for breast cancer; 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. Oestrogel 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. Endometrial hyperplasia and carcinoma: in women with an intact uterus the risk of endometrial hyperplasia and carcinoma is increased when oestrogens are administered for prolonged periods of time. Break through bleeding and spotting may occur during the first months of treatment but if they occur after some time on therapy or continue after treatment has been discontinued the reason should be investigated which may include endometrial biopsy to exclude endometrial malignancy. Unopposed oestrogen stimulation may lead to premalignant or malignant transformation in the residual foci of endometriosis. Breast cancer: evidence shows an increased risk of breast cancer in women taking combined oestrogen-progestogen or oestrogen-only HRT that is dependent on the duration of taking HRT. HRT, especially oestrogen-progestogen combined treatment, increases the density of mammographic images which may adversely affect the radiological detection of breast cancer. Ovarian cancer: evidence suggests a slight increased risk of ovarian cancer in women taking oestrogen-only or combined oestrogen-progestogen HRT which becomes apparent within 5 years of use and diminishes over time after stopping. Venous thromboembolism: HRT is associated with a 1.3 to 3-fold risk of developing venous thromboembolism (i.e. deep vein thrombosis or pulmonary embolism) especially in the first year of use. HRT should be stopped 4 to 6 weeks prior to elective surgery if prolonged immobilisation is to follow. The benefit-risk of HRT should be considered in women already on chronic anticoagulant treatment. If venous thromboembolism occurs during treatment, HRT should be discontinued. Patients should contact their doctors immediately if they have potential thromboembolic symptoms (painful swelling of a leg, sudden chest pain or dyspnoea).

Coronary Artery Disease (CAD): The relative risk of CAD during use of combined oestrogen and progestogen HRT is slightly increased. As the baseline absolute risk of CAD is strongly dependent on age, the number of extra cases of CAD due to oestrogen and progestogen use is very low in healthy women close to menopause, but will rise with more advanced age. Ischaemic stroke: combined oestrogen-progestogen and oestrogen-only therapy are associated with up to a 1.5-fold increase in risk of ischaemic stroke. The risk increases with age. Other conditions: Care should be taken with women with cardiac or renal dysfunction since oestrogens may cause fluid retention. Women with pre-existing hypertriglyceridaemia should be followed closely during oestrogen replacement or HRT since pancreatitis can result from rare cases of large increases in plasma triglycerides. Oestrogens increase binding proteins such as thyroid, corticoid and sex-hormone binding globulins leading to increased circulating hormones. HRT use does not improve cognitive function. There is some evidence of increased risk of probable dementia in women who start HRT after the age of 65. Women using medicinal products containing oestrogens other than ethinylestradiol, such as estradiol, and ombitasvir/paritaprevir/ritonavir and dasabuvir with or without ribavirin had a rate of ALT elevation similar to those not receiving any oestrogens; however, due to the limited number of women taking these other oestrogens, caution is warranted for co-administration with the following combination drug regimens: ombitasvir/paritaprevir/ritonavir and dasabuvir with or without ribavirin, glecaprevir/pibrentasvir, or sofosbuvir/velpatasvir/voxilaprevir.

May cause burning sensation on damaged skin. This product is flammable until dry. Care should be taken to avoid sources of heat or naked flames. FOR THE FULL LIST OF WARNINGS AND PRECAUTIONS PLEASE CONSULT SECTION 4.4 OF THE FULL SPC. **Interactions:** Patients should avoid strong skin cleaners and detergents, skin products of high alcoholic content (e.g. astringents, sunscreens) and keratolytics which may alter the barrier structure or function of the skin. Also, any skin medication which alters skin production (e.g. cytotoxic drugs) should be avoided. The metabolism of oestrogens may be increased, (leading to a decreased effect and changes in the uterine bleeding profile) by enzyme-inducing products (e.g. phenobarbital, phenytoin, carbamazepine, rifampicin, rifabutin, nevirapine, efavirenz). Ritonavir, nelfinavir and St John's wort may also induce the metabolism of oestrogens. As transdermal administration avoids the first pass effect in the liver, transdermally applied oestrogens may be less affected by enzyme inducers than oral hormones. Hormone contraceptives containing oestrogens shown to significantly decrease plasma concentrations of lamotrigine when co-administered. This may reduce seizure control. **Pregnancy, breastfeeding and fertility:** Oestrogel is not indicated in pregnancy or during breastfeeding. Pregnancy should be excluded before initiating HRT If pregnancy occurs during medication with Oestrogel, the treatment should be withdrawn immediately. Fertiliy: not relevant. **Effects on ability to drive and use machines:** No or negligible influence on the ability to drive and use machines **Undesirable effects:** Common adverse drug reactions (≥1/100, <1/10): headache, nausea, abdominal pain, breast swelling/pain, breast enlargement, dysmenorrhoea, menorrhagia, metrorrhagia, leucorrhoea discharge , endometrial hyperplasia, weight change (increase or decrease), water retention with peripheral oedema. Uncommon (≥1/1000, <1/100): depression, mood swings, vertigo, migraine, venous thromboembolic disease, flatulence, vomiting, pruritus, increased volume of uterine fibroids, leiomyoma, vaginitis/vaginal candidiasis, asthenia. Rare (≥1/10000 to ≤1/1000): Glucose intolerance, change in libido, aggravation of epilepsy, arterial hypertension, liver function test abnormalities, cholestasis and jaundice, skin discolouration, acne, bone pain, anaphylactic reaction (in women a history of allergic reaction); Very rare (<1/10,000): contact lens intolerance.

The following risks have been reported: breast cancer; endometrial cancer; ovarian cancer; venous thromboembolism; coronary artery disease; ischaemic stroke. The following adverse reactions have also been reported in association with systemic oestrogen/progestogen treatment: rash, chloasma/ melasma, vomiting, abdominal pain, breast tenderness, breast enlargement, fluid retention/ oedema, weight changes, changes in libido, depression, gall bladder disease, probable dementia over the age of 65, skin and subcutaneous disorders: erythema multiforme, erythema nodosum, vascular purpura. For further information on side effects and risk estimates, please consult the SPC. **Overdose:** Pain in the breasts or excessive production of cervical mucus may be indicative of too high a dosage, but acute overdose has not been reported and is unlikely to be a problem. Overdoses may cause nausea, vomiting and withdrawal bleeding. These signs disappear when the treatment is stopped or when the dose is reduced. There are no specific antidotes and treatment should be symptomatic.

Legal category: POM. **Marketing Authorisation number:** PA 1054/004/001. **Marketing Authorisation Holder :** Laboratoires Besins International, 3 rue du Bourg L'Abbé, 75003 Paris, France.
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Further information is available upon request or in the SmPC.

Adverse events should be reported. Reporting forms and information can be found at www.hpra.ie
Adverse events should also be reported to Besins Healthcare (UK) Ltd, Drug Safety on 01-4004466 or
Email: drugsafety@besins-healthcare.com