ESTOGEL-17 β ESTRADIOL GEL 0.06% w/w

Composition: 17 β Estradiol USP 0.06% w/w Dehydrated Alcohol IP 40.00% w/w Gel base Q.S. The active ingredient of ESTOGEL is 17JI-estradiol. It is chemically and biologically identicallo endogenous humanestradiol. It substitutes for theloss of oestrogen production in menopausalwomen,and alleviates menopausalsymptoms. Indication • Hormone replacement therapy {HRT) for oestrogen deficiency symptoms in postmenopausaJ women. • Prevention of osteoporosis is 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: Generally, when estrogen is prescribed for a postmenopausal woman with a uterus, a progestin should also be considered to reduce the risk of endometrial cancer. A woman without a uterus does not need progestin. The lowest effective dose for the shortest duration should be used. Postmenopausal women should be reevaluated periodically as clinically appropriate to determine if treatment is still necessary. Each pump actuation will deliver 0.75 mg of Estradiol. ESTOGEL as an oestrogen-only product indicated only for women without a uterus. ESTOGEL should be administered daily on a continuous basis. It is recommended to add a progestagen (e.g. a progesterone) for at least 12 days of each month in women with an intact uterus.

Menopausal symptoms:The starting dose is two pump actuations (2.5 g which contains 1.5 mg estradiol) of ESTOGEL once daily. If effective relief is not obtained after one month's treatment, the dosage may be increased to a maximum of four pump actuations (5 g which contains 3.0 mg eastradiol) of ESTOGEL daily.Prevention of osteoporosis: The minimum effective dose is 2.5 g of ESTOGEL once daily for most patients. Unless there is a previous diagnosis of endometriosis, it is not recommended to add a progestagen in hysterectomised women. Initiation of treatment: Women who are post-menopausal or have very infrequent menstrual cycles: Treatment with ESTOGEL can be started on any day. Switching from a continuous oestrogen-progestagen combined HRT: Treatment with ESTOGEL 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 ESTOGEL. Method of Administration: For transdermal use. To obtain a full first dose, it is necessary to prime the canister pump before the first dose, with the canister in the upright position, slowly and fully depress the actuator three times. Safely discard the gel from the first three actuations. After the priming procedure, patients should completely depress the pump one time actuation for every 0.75 mg estradiol required to achieve the daily prescribed dosage. It should be applied to clean, dry, intact areas of skin e.g. on the arms and shoulders, or inner thighs. The area of application should be as large as possible at least 750 cm2. 1 pump actuation of ESTOGEL from the dispenser, or half the prescribed dose, should be applied to each arm/shoulder (or thigh). ESTOGEL should not be applied on or near the breasts or on the vulval region. ESTOGEL should be allowed to dry for 5 minutes before covering the skin with clothing. The ESTOGEL should be applied by the patient herself, not by anyone else, and skin contact, particularly with a male partner, should be avoided for one hour after application. Washing the skin or contact with other skin products should be avoided until at least one hour after application of ESTOGEL. If the patient forgets to apply a dose and it is more than 12 hours until the next dose, the missed dose should be applied and normal dosing resumed the next day. If the next dose is less than 12 hours away, it is best just to wait and apply the next dose normally. Forgetting a dose may increase the likelihood of break-through bleeding and spotting. Contraindications:- Known, past or suspected breast cancer, oestrogen-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 (e.g. angina, myocardial infarction);Acute liver disease, or a history of liver disease as long as liver function tests have failed to return to normal; Known hypersensitivity to the active substances or to any of the excipients;- Porphyria Warning and precautions: In all cases in whom HRT is initiated, a careful appraisal of the risks and benefits should be undertaken at least annually. The risk of endometrial hyperplasia and carcinoma is increased in women with an intact uterus when oestrogens are administered alone for prolonged periods. The overall evidence suggests an increased risk of breast cancer in women taking combined oestrogen-progestagen. HRT is associated with increased risk of developing venous thromboembolism (VTE),i.e. deep vein thrombosis or pulmonary embolism; is more likely in the first year of HRT .There is no evidence of protection against myocardial infarction in women with or without existing CAD who received combined oestrogen progestagen or oestrogen-only HRT. Combined oestrogen-progestagen and oestrogen-only therapy are associated with an increase in risk of ischemic stroke. There is increased risk of dementia in women who use continuous combined or oestrogen-only HRT after the age of 65. HRT use does not improve cognitive function. Drug interactions: Patients should avoid the use of strong skin cleansers and detergents and keratolytics. Treatment with surface active agents, or other drugs which alter barrier structure or function, could remove drug bound to the skin, altering transdermal flux. The metabolism of oestrogens may be increased by concomitant use of drugs known to induce cytochrome P450 enzymes, such as anticonvulsants and anti-infectives (e.g. rifampicin, rifabutin, nevirapine, efavirenz). Ritonavir and nelfinavir, although known as strong inhibitors, by contrast exhibit inducing properties when used concomitantly with steroid hormones. Herbal preparations containing St John's wort (Hypericum perforatum) may induce the metabolism of oestrogens. At transdermal administration, the first-pass effect in the liver is avoided. Therefore transdermally applied oestrogens HRT might be less affected than oral hormones by enzyme inducers. Pregnancy & lactation: ESTOGEL is not indicated during pregnancy. ESTOGEL should be withdrawn immediately if pregnancy occurs during medication with ESTOGEL. The results of most epidemiological studies relevant to inadvertent foetal exposure to oestrogens indicate no teratogenic of foetotoxic effects. ESTOGEL is not indicated during breast-feeding. Effects on ability to drive and use machines None known. Adverse drug reactions: Common Headache, nausea, abdominal pain, breast swelling/pain, breast enlargement, dysmenorrhoea, menorrhagia, metrorraghia, leucorrohoea, endometrial hyperplasia, weight change (increase or decrease), Water retention. Other adverse reactions have been reported in association with oestrogen/progestagen treatment: Gall bladder disease, Skin and subcutaneous disorders: chloasma, erythema multiforme, erythema nodosum, vascular purpura.

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(For the use of a registered medical practitioner or hospital or laboratory only)