

EVALON CREAM

For the use of a Registered Medical Practitioner or Hospital or a Laboratory only.

Abbreviated Prescribing information for EVALON CREAM (Estriol cream)

[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

Mechanism of action: Evalon contains the natural female hormone estriol. Unlike other estrogens, estriol is short acting since it has only a short retention time in the nuclei of endometrial cells. It substitutes for the loss of estrogen production in menopausal women and alleviates menopausal symptoms. Estriol is particularly effective in the treatment of urogenital symptoms. In case of atrophy of the lower urogenital tract estriol induces the normalization of the urogenital epithelium and helps to restore the normal microflora and the physiological pH in the vagina. As a result, it increases the resistance of the urogenital epithelial cells to infection and inflammation reducing vaginal complaints such as dyspareunia, dryness, itching, vaginal and urinary infections, miction complaints and mild urinary incontinence.

DOSAGE AND ADMINISTRATION: As directed by physician.

CONTRAINDICATION: Known or suspected estrogen-dependent malignant. Undiagnosed genital bleeding, Untreated endometrial hyperplasia, Previous or current venous thromboembolism (deep venous thrombosis, pulmonary embolism), Known thrombophilic disorders (e.g. protein C, protein S, or antithrombin deficiency, (see section warnings and precaution), 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 failed to return to normal, Hypersensitivity to the active substance or to any of the excipient, Porphyria, Rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption.

WARNINGS & PRECAUTIONS: For the treatment of postmenopausal symptoms, HRT should only be initiated for symptoms that adversely affect quality of life. Leiomyoma (uterine fibroids) or endometriosis, Risk factors for thromboembolic disorders, Risk factors for estrogen dependent tumors, e.g. 1st degree, heredity for breast cancer, Hypertension, Liver disorders (e.g. liver adenoma), Diabetes mellitus with or without vascular involvement, Cholelithiasis, Migraine or (severe) headache, Systemic lupus erythematosus, A history of endometrial hyperplasia, Epilepsy, Asthma, Otosclerosis. *Reasons for immediate withdrawal of therapy:* Jaundice or deterioration in liver function, Significant increase in blood pressure, New onset of migraine-type headache, Pregnancy. Endometrial hyperplasia and carcinoma, Breast cancer, Ovarian cancer, Venous thromboembolism, Coronary artery disease (CAD), Ischemic stroke.

DRUG INTERACTION: The following interactions have been described with use of combined oral contraceptives which may also be relevant for Evalon. The metabolism of estrogens may be increased by concomitant use of substances known to induce drug-metabolizing enzymes, specifically cytochrome P450 enzymes, such as 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 estrogens. Clinically, an increased metabolism of estrogens may lead to decreased effect and changes in the uterine bleeding profile.

ADVERSE REACTIONS: Fluid retention, Nausea, Breast discomfort and pain, Postmenopausal spotting, Cervical discharge, Flu-like symptoms. estrogen/ progestagen treatment: Estrogen-dependent neoplasms benign and malignant, e.g. endometrial cancer, Gall bladder disease, Skin and subcutaneous disorders: chloasma, erythema, multiforme, erythema nodosum, vascular purpura, Probable dementia over the age of 65. Breast cancer risk, Ovarian cancer, Risk of venous thromboembolism, Coronary artery disease (CAD), Ischemic stroke.

MARKETED BY



TORRENT PHARMACEUTICALS LTD.

IN/Evalon Cream 1 mg/MAY-21/01/ABPI
(Additional information is available on request)