EVADIOL

Composition: Each film coated tablet contains: Estradiol Valerate USP 2 mg, Colour: Indigo Carmine, Titanium Dioxide IP, Excipients: Q.S. Description: Evadiol tablet contains estradiol valerate. Estradiol valerate, is the valeric-acid ester of the endogenous female oestrogen, estradiol. Each pack contains 28 tablets each containing estradiol valerate 2.0 mg. Indications: Hormone replacement therapy (HRT) for oestrogen deficiency symptoms in peri- and postmenopausal women. 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. Contraindications: Known, past or suspected breast cancer. Known or suspected oestrogen-dependent malignant tumours e.g. endometrial cancer. Undiagnosed genital bleeding. Untreated endometrial hyperplasia. Previous idiopathic or current venous thromboembolism. (deep venous thrombosis, pulmonary embolism) ,Known thrombophilic disorders (e.g. protein C, protein S, or antithrombin deficiency) 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. Porphyria. Known hypersensitivity to the active substances or to any of the excipients. Dosage and administration: One tablet of estradiol valerate (2mg) to be taken daily at same time every day. Treatment is continuous, which means that the next pack follows immediately without a break. For initiation and continuation of treatment of menopausal symptoms, the lowest effective dose for the shortest duration should be used. Treatment to control menopausal symptoms should be initiated with Estradiol valerate 1mg. If considered necessary, Estradiol valerate 2mg should be used. Once treatment is established the lowest effective dose necessary for relief of symptoms should be used.For prevention of postmenopausal osteoporosis one tablet of Estradiol valerate 2mg is to be taken daily. In women with an intact uterus, a progestogen should beadded to Estradiol valerate for at least 12 - 14 days each month. Unless there is a previous diagnosis of endometriosis, it is not recommended to add a progestogen in hysterectomised women. How to start estradiol valerate: If the woman has an intact uterus and is still menstruating, a combination regimen with Estradiol valerate and a progestogen, commencing with the oestrogen phase, should begin on the first day of bleeding. If the menstrual periods are very infrequent or if amenorrhoea is established, she may start at any time provided, if appropriate, pregnancy has been excluded. In women transferring from a continuous combined HRT product, treatment with Estradiol valerate may be started on any day. In women transferring from cyclic or continuous sequential HRT regimens, the woman should complete the cycle and then change to Estradiol valerate without a break in therapy. Missed or lost tablets: If the woman forgets to take a tablet at the usual time, she may take it within the following 12 hours. If the woman is more than 12 hours late the forgotten tablet should not be taken and the remaining tablets taken at the usual time on the right days. A missed dose may lead to breakthrough bleeding or spotting. Children: Not recommended for children Warnings and precautions for use: For the treatment of postmenopausal symptoms, HRT should only be initiated for symptoms that adversely affect quality of life. HRT is associated with a higher relative risk of developing venous thromboembolism (VTE), i.e. deep vein thrombosis or pulmonary embolism. probable dementia in women who start using continuous combined CEE and MPA after the age of 65. ESTRADIOL VALERATE is not suitable as a contraceptive. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine. Drug Interaction: The metabolism of oestrogens may be increased by concomitant use of substances known to induce drug-metabolising enzymes, specifically cytochrome P450 enzymes, such as anticonvulsants (e.g. phenobarbitol, phenytoin, carbamazepine) 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. Clinically, an increased metabolism of oestrogens and progestogens may lead to decreased effect and changes in the uterine bleeding profile. Pregnancy and lactation: It is not indicated during pregnancy. If pregnancy occurs during treatment, it should be withdrawn immediately. The results of most epidemiological studies to date relevant to inadvertant foetal exposure to oestrogens indicate no teratogenic or foetotoxic effects. It is not indicated during lactation. Side effects: Reproductive system and breast disorders: Changes in vaginal bleeding pattern and abnormal bleeding or flow, breakthrough bleeding, spotting (bleeding irregularities usually subside during continued treatment), dysmenorrhoea, changes of vaginal secretion, premenstrual-like syndrome, breast tenderness, enlargement or pain, increased size of uterine fibroids, vaginal candidosis, changes in cervical erosion, breast secretion. Gastrointestinal disorders: Dyspepsia, bloating, flatulence, nausea, vomiting, abdominal pain, gall bladder disease including cholestasis. Skin and subcutaneous tissue disorders: Rashes, various skin disorders (including pruritus, eczema, urticaria, acne, hirsutism, hair loss, erythema nodosum, erythema multiforme, haemorrhagic erruption), chloasma. Nervous system disorders: Headache, migraine, dizziness, anxiety/depressive symptoms, fatigue.Cardiovascular disorders: Palpitations, hypertension, thrombophlebitis.. Breast cancer: According to evidence from a large number of epidemiological studies and the Women's Health Initiative (WHI), the overall risk of breast cancer increases with increasing duration of HRT use in current or recent HRT users. Endometrial cancer: In women with an intact uterus, the risk of endometrial hyperplasia and endometrial cancer increases with increasing duration of use of unopposed oestrogens. Overdose: Nausea and vomiting may occur with an overdose. There are no specific antidotes, and treatment should be symptomatic. Withdrawal bleeding may occur in females with a uterus. (For details, please refer full prescribing information)

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