

MyEstra™

Estradiol valerate 1mg/2mg

Therapeutic indications: Hormonal replacement therapy: For the treatment of signs and symptoms of estrogen deficiency due to natural menopause.

Dosage and Administration: Before starting MyEstra™ a thorough general medical and gynecological examination (including the breasts) should be carried out. Unless otherwise prescribed by the doctor, 1 tablet MyEstra™ 2 mg is taken daily after a meal. MyEstra™ may be prescribed cyclically (21 – days treatment 1 week gap, in which after each 21-day regimen there must be a pause in tablet-taking of at least 1 week) or continuous. In the course of treatment, the doctor may decide to reduce the dose to 1 tablet MyEstra™, 1 mg daily. Under this lower dose, too, a tablet-free interval of at least 1 week should be observed after each 21-day regimen. As a general rule, MyEstra™ treatment should be discontinued every 6 months in order to verify the persistence of complaints requiring treatment.

Special warnings and precautions for use: For the treatment of postmenopausal symptoms, HRT should only be initiated for symptoms that adversely affect quality of life. In all cases, a careful appraisal of the risks and benefits should be undertaken at least annually and HRT should only be continued as long as the benefit outweighs the risk. **Pregnancy and Lactation:** Not for use during pregnancy. **Paediatric population:** Not to be used in children. **Contraindications:** Pregnancy; severe disturbances of liver function; jaundice or persistent itching during a previous pregnancy; Dubin-Johnson syndrome; Rotor syndrome; previous or existing liver tumours; existing or previous thromboembolic processes (e.g. stroke, myocardial infarction); sickle-cell anaemia; existing or suspected hormone-dependent tumours of the uterus; endometriosis; severe diabetes with vascular changes; congenital disturbances of lipid metabolism; otosclerosis with deterioration in previous pregnancies. **Drug interactions:** Significant drug-drug interactions are apparent when CYP3A4 modulators are co-administered with rifampicin, erythromycin, ketoconazole. Estradiol valerate may interact with drugs like carbamazepine, efavirenze, nelfinavir, nevirapine, phenobarbital, phenytoin, rifabutin, rifampicin and ritonavir; and classes of drugs like anticoagulants, anticonvulsants, CYP450 enzyme inducers.

Adverse reactions: Breast pain or discomfort, headache, increase in body weight, stomach upset, nausea and vomiting and uterine bleeding can occur.

Dosage Forms and Strengths: MyEstra™ 1mg is available as 1 mg tablets in blister pack of 14's. MyEstra 2 mg is available as 2 mg tablets in blister pack of 14's.

Storage: Store in cool place, protected from light and moisture. Keep out of reach of children

Manufactured by: Akums Drugs & Pharmaceuticals Ltd, At: Plot No. 26A-30, Sector-8A, I.I.E., SIDCUL, Ranipur, Haridwar-249 403, Uttarakhand, India.20068167

Marketed in India by: Mylan Pharmaceuticals Private Limited, Plot No. 1-A/2, MIDC Industrial Estate, Taloja, Panvel, District Raigad, Maharashtra – 410 208, India.

Abbreviated Prescribing Information Version 12/2016.

Please refer to the full Prescribing Information before prescribing MyEstra™, available on request from Mylan Pharmaceuticals Private Limited, 10th Floor, Prestige Platina, Block 3, Kadubeesanahalli Village, Varthur Hobli, Outer Ring Road, Bangalore 560 087.