

ValenaTM CREAM

Estradiol 0.01%

Presentation

ValenaTM cream: Each gram cream contains Estradiol BP 0.1 mg.

Description

Endogenous estrogens are largely responsible for the development and maintenance of the female reproductive system and secondary sexual characteristics. Although circulating estrogens exist in a dynamic equilibrium of metabolic interconversions, estradiol is the principal intracellular human estrogen and is substantially more potent than its metabolites, estrone and estriol at the receptor level.

Indications and Uses

ValenaTM (estradiol vaginal cream, 0.01%) is indicated in the treatment of moderate to severe symptoms of vulvar and vaginal atrophy due to menopause.

Dosage and Administration

The usual dosage range is 2 to 4 g (marked on the applicator) daily for one or two weeks, then gradually reduced to one half initial dosage for a similar period. A maintenance dosage of 1g, one to three times a week, may be used after restoration of the vaginal mucosa has been achieved.

Side Effects

Headache, Breast pain, Irregular vaginal bleeding or spotting, Stomach or abdominal cramps, bloating, Nausea and vomiting, Hair loss, Fluid retention, Vaginal yeast infection. Reactions from inserting ValenaTM Vaginal Cream, such as vaginal burning, irritation, itching etc.

Precautions

Patient taking an additional progestin with ValenaTM may have endometrial hyperplasia which is a precursor to endometrial cancer. These include a possible increased risk of breast cancer. Patients may also face Elevated Blood Pressure, Hypertriglyceridemia (If she has pre-existing hypertriglyceridemia). Caution should be taken for patients who have Hepatic Impairment and/or Past History of Cholestatic Jaundice, Hypothyroidism, Hypocalcemia. Estrogen may cause exacerbation of endometriosis, asthma, diabetes mellitus, epilepsy, migraine or porphyria, systemic lupus erythematosus, and hepatic hemangiomas. So, ValenaTM should be used with caution in women with these conditions.

Contraindications

ValenaTM is contraindicated in women with Undiagnosed abnormal genital bleeding, Known or suspected or history of cancer of the breast, Known or suspected estrogen-dependent neoplasia, Active DVT, PE or history of these conditions, Active arterial thromboembolic disease (for example, stroke, MI) or a history of these conditions, Known anaphylactic reaction or angioedema to estradiol vaginal cream BP, 0.01%), Known liver dysfunction or disease, Known protein C, protein S, or antithrombin deficiency, or other thrombophilic disorders, Known or suspected pregnancy.

Use in Pregnancy and Lactation

ValenaTM should not be used during pregnancy. There appears to be little or no increased risk of birth defects in children born to women who have used estrogens and progestins as an oral contraceptive inadvertently during early pregnancy.

Use in Children

ValenaTM vaginal cream is not indicated in children. Clinical studies have not been conducted in the pediatric population.

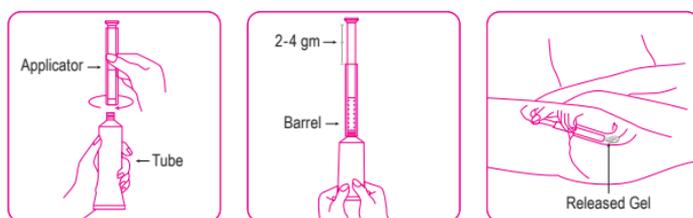
Drug Interaction

Phenobarbital, Carbamazepine, and Rifampin may reduce plasma concentrations of estrogens, possibly resulting in a decrease in therapeutic effects and/or changes in the uterine bleeding profile. Erythromycin, Clarithromycin, Ketoconazole, Itraconazole, Ritonavir and Grapefruit juice may increase plasma concentrations of estrogens and may result in side effects.

Overdosage

Overdosage of estrogen may cause nausea, vomiting, breast tenderness, abdominal pain, drowsiness and fatigue, and withdrawal bleeding may occur in women. Treatment of overdose consists of discontinuation of ValenaTM therapy together with institution of appropriate symptomatic care.

Instructions for Applicator Use



Step 1: Wash hand thoroughly with soapy water

Step 2: Open the sealed wrapper and remove the applicator

Step 3: Insert the tip of the applicator into the tube

Step 4: Press down the tube and squeeze the specified amount of gel (2gm - 4gm indicated marking) into the applicator tube

Step 5: Remove the applicator from the tube

Step 6: Gently insert the rounded tip of the applicator into vagina

Step 7: Push the plunger to release the gel

Step 8: After releasing the gel remove the applicator, keep the applicator clean and germfree for later use

Storage

Do not store above 30°C. Keep away from light and out of the reach of children.

Commercial pack

ValenaTM cream: Each pack contains 16 gm of Estradiol 0.01% vaginal cream and a vaginal applicator.