

FemastinTM Cream

Estriol USP 0.1% (1 mg per 1 gm)

COMPOSITION

FemastinTM Cream: Each gm of cream contains Estriol USP 1 mg.

Pharmacology

FemastinTM Cream is a Hormone Replacement Therapy (HRT). It contains the female hormone estriol (an estrogen). During menopause **FemastinTM (Estriol)** is used in vagina which is slowly released and absorbed into the surrounding area and into the bloodstream.

INDICATION

FemastinTM cream is indicated for the deficiency of estrogen. During menopause, the amount of estrogens produced by a woman's body gradually drops. Shortage of estrogens causes the vaginal wall to become thin and dry which leads to painful sexual intercourse. **FemastinTM cream** is used to relieve painful sexual intercourse. **FemastinTM** is used in postmenopausal women with at least 12 months since their last natural period. If the ovaries are removed surgically (ovariectomy) before menopause, the decrease in estrogen production occurs very abruptly.

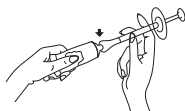
DOSAGE AND ADMINISTRATION

FemastinTM cream should be used as per physician's advice. Each dose of cream contains 0.5 mg estriol. For vulvo-vaginal complaints associated with menopause: Initially one dose of cream per day for 3 weeks. Later you may only need one dose of cream twice a week.

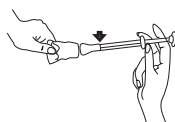
Before surgery: One dose of cream daily 2 weeks before the operation. When having a Pap smear your doctor may recommend a daily application of cream for 7 days.

How to apply the cream: One application (applicator filled to the ring mark) contains 0.5 gm of FemastinTM cream, which contains 0.5 mg estriol.

1. Remove cap from the tube, invert it, and use the sharp point to open the tube.
2. Pull the plunger up to the ring. Now attach it to the opening of the tube.



3. Squeeze the tube slowly to fill the applicator to the ring-mark (where the plunger stops).



4. Remove the tube.
5. To apply the cream, lie down; insert the applicator deep into the vagina.
6. Slowly push the plunger all the way in until the applicator is empty.



7. After use, pull the plunger out of the barrel beyond the point of resistance and wash both parts in warm, soapy water. Do not use detergents. Rinse well and dry afterwards. Do not put the applicator in hot or boiling water.
8. The applicator can be re-assembled by fully inserting the plunger into the barrel beyond the point where resistance is felt. Discard the applicator once the tube is empty. Take FemastinTM cream before taking rest or going to sleep. If you forget a dose, use it as soon as you remember. But if you remember your missed dose at the time of your next dose, do not use an extra dose. Do not use a double dose to make up for the missed dose. This may increase the chance of you getting an unwanted side effect.

PRECAUTION

Patients should keep under doctor's observation for any Hormone Replacement Therapy (HRT). Same role is applicable for the application of **FemastinTM cream**. Doctor will give continuous advice regarding risks & benefits of the drug. But in case of jaundice, sudden high blood pressure, migraine, severe headache or pregnancy, the use of FemastinTM cream will be stopped immediately. Children's are not allowed to use FemastinTM cream.

SIDE EFFECT

Local irritation or itching of vagina, Swelling and increased tenderness of the breasts, Increased vaginal discharge, Nausea, Fluid retention in the tissues, usually marked by swollen ankles or feet. In most patients these side effects will disappear after the first weeks of treatment. Tell your doctor if vaginal bleeding occurs or if any side effect becomes troublesome or persists. Other side effects which may occur with HRT are benign and malignant hormone-dependent tumors such as endometrial cancer, heart attack and stroke, gall bladder disease, skin problems such as rashes, discoloration or red patches on the skin, various skin diseases with blisters and nodules or bleeding into the skin, venous thromboembolism or deep leg or pelvic venous thrombosis and pulmonary embolism (see Before you use FemastinTM Cream). Using HRT for several years slightly increases the risk of breast cancer.

CONTRAINDICATION

Do not use FemastinTM Cream if:

- You have or have ever had breast cancer, or if you are suspected of having it, ovarian cancer, heart attack, stroke, angina, liver disease, thrombosis, pulmonary embolism, vaginal cancer.
- You are pregnant or think you may be pregnant
- You have any unexplained vaginal bleeding, blood clotting disorder, endometrial hyperplasia, porphyria, and various kind of allergic reaction.
- Jaundice, migraine pain, high blood pressure & breathing problem
- You have had an allergic reaction to estriol, or any of the other ingredients of FemastinTM

USE IN PREGNANCY & LACTATION

This medicine is contraindicated during pregnancy & lactation.

DRUG-DRUG INTERACTION

Interaction is found with Anticoagulants, corticosteroid hormones, succinylcholine, theophyllines, and medicines for epilepsy, medicines for fungal or bacterial infections, viral infections, and herbal preparations containing St John's Wort. As a result irregular bleeding may occur.

STORAGE

Store below 25°C. Protect from light and moisture. Keep out of reach of children.

HOW SUPPLIES

FemastinTM cream: Each pack has aluminium tube containing 15 gm cream with a dedicated applicator.

Manufactured by



SQUARE
PHARMACEUTICALS LTD.
BANGLADESH