

# Brightside Specialty Pharmacy

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## Patient Education for PREMARIN VAGINAL CREAM-APPL



If available, dispense patient package insert and explain to pt Keep all medical appointments Physician must know patient's complete medical history Instruct patient on proper administration of medication Complications may occur if current therapy is undisclosed. Smoking increases risk of severe cardiovascular problems. May increase risk of malignancy and cardiovascular disease. Not recommended during pregnancy.

If available, read the patient package insert Keep all medical appointments Tell doctor your complete medical history Learn how to correctly use this medicine Tell Dr/dentist on drug prior to any surgery. Not smoking lowers risk for heart attack/stroke. See doctor regularly for examinations. Not recommended during pregnancy.

### .....Education Section.....

#### **IMPORTANT:**

HOW TO USE THIS INFORMATION: This is a summary and

does NOT have all possible information about this product. This information does not assure that this product is safe, effective, or appropriate for you. This information is not individual medical advice and does not substitute for the advice of your health care professional. Always ask your health care professional for complete information about this product and your specific health needs.

ESTROGENS CREAM - VAGINAL

(ES-troe-jenz)

#### **WARNING:**

Estrogens, either used alone or with another hormone

(progestin), have rarely caused very serious side effects.

Discuss the risks and benefits of hormone treatment with your doctor. Estrogens should not be used to prevent heart disease or dementia.

Estrogens can increase the risk of cancer of the uterus (endometrial cancer). Taking a progestin as directed by your doctor can help decrease this risk. Tell your doctor right away if you have any unusual vaginal bleeding.

In postmenopausal women, estrogens, taken with or without a progestin, increase the risk of cancer of the breast/ovaries, stroke, dementia, and serious blood clots. When used along with a progestin, estrogens also increase the risk of heart disease (such as heart attacks).

The risk for serious side effects may depend on the dose of estrogen and the length of time it is used. This medication should be used at the lowest effective dose and for the shortest amount of time. Discuss the use of this medication with your doctor and check with him/her regularly (for example, every 3 to 6 months) to see if you still need to use this medication. If you will be using this medication long-term, you should have regular complete physical exams (for example, once a year) as directed by your doctor. See also Notes section.

#### **USES:**

This medication is a female hormone. It is used by women

to help reduce vaginal symptoms of menopause (such as vaginal dryness/burning/itching). These symptoms are caused by the body making less estrogen. When treating only vaginal symptoms of menopause, products applied directly inside the vagina (such as this medication) should be used first. Estrogens that are taken by mouth, absorbed through the skin, or injected may have greater risks of side effects due to more estrogen being absorbed.

#### **OTHER USES:**

This section contains uses of this drug that are not

listed in the approved professional labeling for the drug but that may be prescribed by your health care professional. Use this drug for a condition that is listed in this section only if it has been so prescribed by your health care professional.

This medication may also be used for a certain condition in which the labia stick together (labial adhesion).

#### **HOW TO USE:**

Read the Patient Information Leaflet if available

from your pharmacist before you start using this medication and each time you get a refill. If you have any questions, ask your doctor or pharmacist.

Use this medication as directed by your doctor. Fill the applicator with the medication according to the directions. Insert the applicator high into the vagina and press the plunger to release the medication. Clean the applicator with warm soapy water and rinse well. Do not boil or use hot water to clean the applicator.

The dosage is based on your medical condition and response to treatment.

Use this medication regularly to get the most benefit from it. Follow your dosing schedule carefully. Do not increase your dose or use this medication more often or for a longer time than directed.

Tell your doctor if your condition does not improve or if it worsens.

#### **SIDE EFFECTS:**

See also Warning section.

Nausea/vomiting, bloating, breast tenderness, headache, or

weight changes may occur. If any of these effects last or get worse, tell your doctor or pharmacist promptly.

Remember that this medication has been prescribed because your doctor has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects.

Tell your doctor right away if you have any serious side effects, including: nausea/vomiting that doesn't stop, mental/mood changes (such as depression, memory loss), breast lumps, unusual vaginal bleeding (such as spotting, breakthrough bleeding, prolonged/recurrent bleeding), increased or new vaginal irritation/itching/odor/discharge, severe stomach/abdominal pain, yellowing eyes/skin, dark urine, swelling hands/ankles/feet, increased thirst/urination.

This medication may rarely cause serious problems from blood clots (such as heart attacks, strokes, deep vein thrombosis, pulmonary embolism). Get medical help right away if you have any serious side effects, including: chest/jaw/left arm pain, unusual sweating, sudden/severe headache, weakness on one side of the body, confusion, trouble speaking, sudden vision changes (such as partial/complete blindness), pain/redness/swelling of legs, tingling/weakness/numbness in the arms/legs, trouble breathing, coughing up blood, sudden dizziness/fainting.

A very serious allergic reaction to this product is rare. However, get medical help right away if you notice any symptoms of a serious allergic reaction, including: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing.

This is not a complete list of possible side effects. If you notice other effects not listed above, contact your doctor or pharmacist.

In the US -

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or at [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

In Canada - Call your doctor for medical advice about side effects. You may report side effects to Health Canada at 1-866-234-2345.

#### **PRECAUTIONS:**

Before using this medication, tell your doctor or

pharmacist if you are allergic to it; or if you have any other allergies. This product may contain inactive ingredients, which can cause allergic reactions or other problems. Talk to your pharmacist for more details.

Before using this medication, tell your doctor or pharmacist your medical history, especially of: vaginal bleeding of unknown cause, certain cancers (such as breast cancer, cancer of the uterus/ovaries), blood clots, stroke, heart disease (such as heart attack), liver disease, kidney disease, family medical history (especially breast lumps, cancer, blood clots), family or personal history of a certain swelling disorder (angioedema), blood clotting disorders (such as protein C or protein S deficiency), high blood pressure, diabetes, high cholesterol/triglyceride levels, obesity, lupus, underactive thyroid (hypothyroidism), mineral imbalance (low or high level of calcium in the blood), a certain hormone problem

(hypoparathyroidism), uterus problems (such as fibroids, endometriosis), gallbladder disease, asthma, seizures, migraine headaches, mental/mood disorders (such as dementia, depression), certain blood disorder (porphyria).

Do not smoke or use tobacco. Estrogens combined with smoking further increases your risk of stroke, blood clots, high blood pressure, and heart attack, especially in women older than 35.

Tell your doctor if you just had or will be having surgery, or if you will be confined to a chair or bed for a long time (such as a long plane flight). These conditions increase your risk of getting blood clots, especially if you are using an estrogen product. You may need to stop this medication for a time or take special precautions.

This medication may cause blotchy, dark areas on your face and skin (melasma). Sunlight may worsen this effect. Limit your time in the sun. Avoid tanning booths and sunlamps. Use sunscreen and wear protective clothing when outdoors.

If you are nearsighted or wear contact lenses, you may develop vision problems or trouble wearing your contact lenses. Contact your eye doctor if these problems occur.

Some estrogen products contain mineral oil which can weaken rubber products such as latex condoms, cervical caps, and diaphragms and lead to their failure. Consult your pharmacist if you are unsure if your product contains mineral oil. If it does, talk to your doctor about other birth control products (such as polyurethane condoms) while you are using this medication.

This medication should not be used during pregnancy. If you become pregnant or think you may be pregnant, tell your doctor right away.

This medication passes into breast milk. It may reduce the quality and amount of breast milk produced. Consult your doctor before breast-feeding.

#### **DRUG INTERACTIONS:**

Drug interactions may change how your

medications work or increase your risk for serious side effects.

This document does not contain all possible drug interactions.

Keep a list of all the products you use (including prescription/nonprescription drugs and herbal products) and share it with your doctor and pharmacist. Do not start, stop, or change the dosage of any medicines without your doctor's approval.

Some products that may interact with this drug include: aromatase inhibitors (such as anastrozole, exemestane, letrozole), fulvestrant, ospemifene, raloxifene, tamoxifen, toremifene, tranexamic acid.

This medication may interfere with certain laboratory tests (including metyrapone test), possibly causing false test results. Make sure laboratory personnel and all your doctors know you use this drug.

#### **OVERDOSE:**

This medicine may be harmful if swallowed. If someone

has overdosed and has serious symptoms such as passing out or trouble breathing, call 911. Otherwise, call a poison control center right away. US residents can call their local poison control center at 1-800-222-1222. Canada residents can call a provincial poison control center. Symptoms of overdose may

include: severe nausea/vomiting, unusual vaginal bleeding.

**NOTES:**

Do not share this medication with others.

Keep all regular medical and laboratory appointments. You should have regular complete physical exams (for example, once a year) which include laboratory and medical tests (such as blood pressure, breast exam/mammogram, pelvic exam, pap smear) to monitor your progress and check for side effects. Follow your doctor's instructions for examining your own breasts, and report any lumps right away. Consult your doctor for more details.

Preventing or controlling high blood pressure, high cholesterol, and diabetes can help to reduce your chances of heart disease and stroke. Lifestyle changes that can help to control or prevent these diseases include reducing stress, eating a low fat/salt diet, losing weight if overweight, exercising regularly, and stopping smoking. Keep your mind active with mental exercises (such as reading, solving crossword puzzles) to help prevent dementia. Talk to your doctor about lifestyle changes that might benefit you.

**MISSED DOSE:**

If you miss a dose, use it as soon as you remember.

If it is near the time of the next dose, skip the missed dose. Use your next dose at the regular time. Do not double the dose to catch up.

**STORAGE:**

Store at room temperature. Keep all medications away

from children and pets.

Do not flush medications down the toilet or pour them into a drain unless instructed to do so. Properly discard this product when it is expired or no longer needed. Consult your pharmacist or local waste disposal company.

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