

# Patient Information and How to Use ECOZA (ee-ko-zah) (econazole nitrate) topical foam, 1%

- **Important information:** ECOZA topical foam is for use on skin only. Do not use ECOZA topical foam in your eyes or vagina.
- **What is ECOZA topical foam?**

ECOZA topical foam is a prescription medicine used on the skin (topical) to treat athlete's foot that is between the toes (interdigital tinea pedis) in people 12 years of age and older.
- **What should I tell my doctor before using ECOZA topical foam?**

Before using ECOZA topical foam, tell your doctor about all of your medical conditions, including if you:

  - are pregnant or plan to become pregnant. It is not known if ECOZA topical foam will harm your unborn baby.
  - are breastfeeding or plan to breastfeed. It is not known if ECOZA topical foam passes into your breast milk.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.
- **How should I use ECOZA topical foam?** See the detailed Instructions for Use for information about how to use ECOZA topical foam.
  - Use ECOZA topical foam exactly as your doctor tells you to use it.
  - Apply ECOZA topical foam to the affected skin areas of your feet 1 time a day for 4 weeks.
  - If ECOZA topical foam gets in or near your eyes, rinse them well with water.
  - Wash your hands after you apply ECOZA topical foam.
- **What should I avoid while using ECOZA topical foam?**
  - ECOZA topical foam is flammable. Avoid heat, flame and smoking while applying and right after you apply ECOZA topical foam to your skin.
- **What are the possible side effects of ECOZA topical foam?**

ECOZA topical foam may cause skin reactions at the treatment site. Tell your doctor if you have any skin reactions on the areas of your skin treated with ECOZA topical foam. These are not all the possible side effects of ECOZA topical foam. Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.
- **How should I store ECOZA topical foam?**
  - Store ECOZA topical foam at room temperature, between 68°F to 77°F (20°C to 25°C).
  - Do not refrigerate or freeze ECOZA topical foam.
  - Do not store ECOZA topical foam in direct sunlight.
  - ECOZA topical foam is flammable. Keep the ECOZA topical foam canister away from heat and temperatures above 120°F (49°C), even if the canister is empty.
  - Do not puncture or burn the ECOZA topical foam canister.

**Keep ECOZA topical foam and all medicines out of the reach of children.**

## DOSAGE AND ADMINISTRATION

ECOZA is for topical use only. It is not for oral, ophthalmic, or intravaginal use. ECOZA should be applied to cover affected areas once daily for 4 weeks.

## IMPORTANT SAFETY INFORMATION

### INDICATIONS AND USAGE

ECOZA is an azole antifungal indicated for the treatment of interdigital tinea pedis caused by *Trichophyton rubrum*, *Trichophyton mentagrophytes*, and *Epidermophyton floccosum* in patients 12 years of age and older.

**PLEASE SEE COMPLETE PRESCRIBING INFORMATION AND REVERSE FOR ADDITIONAL IMPORTANT SAFETY INFORMATION.**



**ecoza**<sup>®</sup>  
(econazole nitrate)  
topical foam, 1%

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# Instructions for Use

## ECOZA (ee-ko-zah) (econazole nitrate) topical foam, 1%



Figure A  
Parts of Ecoza topical foam canister

### How to apply ECOZA topical foam:

- Step 1:** Before applying, shake the ECOZA topical foam canister for about 5 seconds.
- Step 2:** Remove cap and turn canister upside down over the palm of your hand. (See Figure B)
- Step 3:** Press down firmly on the actuator (See Figure A) until there is a golf ball-sized amount of foam in the palm of your hand. (See Figures B and C)
- Step 4:** Use your fingertips to scoop up small amounts of ECOZA topical foam and apply to the affected skin areas on your feet. Gently rub the foam into the skin. (See Figure D)
- Apply ECOZA topical foam to your toes, to the spaces between your toes, and to surrounding areas 1 time a day for 4 weeks or as prescribed by your doctor.
- Step 5:** Replace the cap. Wash your hands after applying ECOZA topical foam.



Figure B

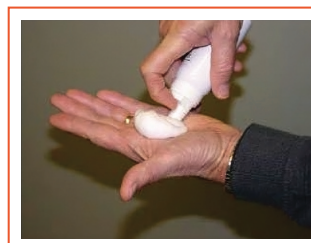


Figure C

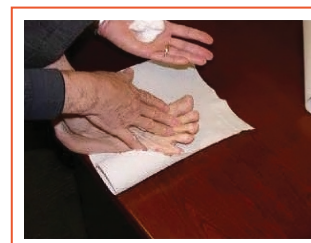


Figure D

### General information about the safe and effective use of ECOZA topical foam

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. You can ask your doctor or pharmacist for information about ECOZA topical foam that is written for health professionals. Do not use ECOZA topical foam for a condition for which it was not prescribed. Do not give ECOZA topical foam to other people, even if they have the same symptoms that you have. It may harm them.

### Ingredients in ECOZA topical foam

Active ingredient: econazole nitrate.

Inactive ingredients: dimethicone, glycerin, polysorbate 20, povidone, propylene glycol, stearic acid, trolamine, purified water and butane as a propellant.

### IMPORTANT SAFETY INFORMATION

#### ADVERSE REACTIONS

#### CLINICAL TRIALS EXPERIENCE:

During clinical trials with ECOZA topical foam, 1%, the most common adverse reactions were application site reactions which occurred in less than 1% of subjects in both the ECOZA and vehicle arms.

#### DRUG INTERACTIONS

**Warfarin:** Concomitant administration of econazole and warfarin has resulted in enhancement of anticoagulant effect. Most cases reported product application with use under occlusion, genital application, or application to a large body surface area which may increase the systemic absorption of econazole nitrate. Monitoring of International Normalized Ration (INR) and/or prothrombin time may be indicated especially for patients who apply econazole to large body surface areas, in the genital area, or under occlusion.

#### WARNINGS AND PRECAUTIONS

**Flammability:** ECOZA topical foam is flammable. Avoid heat, flame, and smoking during and immediately following application. Contents under pressure. Do not puncture and/or incinerate the containers. Do not expose containers to heat and/or store at temperatures above 120°F (49°C), even when empty. Do not store in direct sunlight.

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