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 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 is 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 FDA at 1-800-FDA-1088.

How should I use 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.

Ecoza topical foam is flammable. Keep the ecoza topical foam canister away from heat sources 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.

Important information: Ecoza topical foam is for use on skin only. Do not use Ecoza topical foam in your eyes or vagina.

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 medicines which 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.

What are the ingredients in Ecoza topical foam?

Active ingredients: econazole nitrate

Inactive Ingredients: dimethicone, glycerol, polysorbate 20, propylene glycol, stearic acid, trolamine, purified water and butane as a propellant.

Manufactured in the USA by Givneux Pharmaceuticals, LLC. Jamison, PA 18929

For more information call Givneux Pharmaceuticals, LLC at 1-877-660-6263.

The Patient Information has been approved by the U.S. Food and Drug Administration. Issued 10/2013
How to apply Ecoza topical foam:

Step 1: Before you apply Ecoza topical foam, shake the Ecoza topical foam canister for about 5 seconds.

Step 2: Remove the cap and turn the Ecoza topical foam canister upside down over your palm of hand. (See Figures B and C)

Step 3: Press down firmly on the actuator until there is a small amount of foam about the size of a golf ball in the palm of your hand. (See Figures B and C)

Step 4: Use your finger-tips to scoop up small amounts of Ecoza topical foam and apply to the affected skin areas on your foot. Gently rub the foam into the skin. (See Figure D)

Step 5: You should apply Ecoza topical foam to your toes, to the spaces between your toes, and to the surrounding areas 1 time a day for 4 weeks or as prescribed by your doctor.

Step 6: Replace the cap. Wash your hands after applying Ecoza topical foam.

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.

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

Manufactured in the USA for Quinnova Pharmaceuticals, LLC Jamison, PA 18049

Issued: 10/2013

Instructions for Use}

Quinnova Pharmaceuticals, LLC
Manufactured in the USA for Quinnova Pharmaceuticals, LLC Jamison, PA 18049

19 HOW SUPPLIED/ STORAGE AND HANDLING

Ecoza topical foam, 1% is white to off-white foam supplied in 70 g (NDC 20710-100-70) aluminum pressurized canister.

Store at controlled room temperature 20°C to 25°C (68°F to 77°F) with excipients permitted between 10°C and 30°C (50°F and 86°F). Do not refrigerate or freeze.

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 store in direct sunlight.

17 PATIENT COUNSELING INFORMATION

See FDA-approved patient labeling (Patient Information)

The patient should be instructed as follows:

• Inform patients that Ecoza (econazole nitrate) topical foam, 1% is for topical use only. Ecoza (econazole nitrate) topical foam, 1% is not intended for oral, intravaginal, or ophthalmic use.
• Ecoza topical foam, 1% is flammable; avoid heat, flame, and smoking during and immediately following application.
• If a reaction suggesting sensitivity or chemical irritation develops with the use of Ecoza topical foam, 1%, use of the medication should be discontinued.

Manufactured in the USA for Quinnova Pharmaceuticals, LLC Jamison, PA 18049

U.S. Patent 5,920,830

140156-1113

12.4 Microbiology

Mechanism of Action

Econazole nitrate, an azole antifungal agent, inhibits fungal cytochrome P-450-mediated 14 alpha-lanosterol demethylase enzyme. This enzyme functions to convert lanosterol to ergosterol. The accumulation of 14 alpha-methyl sterols correlates with the subsequent loss of ergosterol in the fungal cell wall and ergosterol is responsible for the fungistatic activity of econazole. Mammalian cell demethylases is less sensitive to econazole inhibition.

• Activity in vitro and in clinical infections

Econazole nitrate has been shown to be active against most strains of the following microorganisms, both in vitro and in clinical infections (see Indications and Usage/7). Glucocorticoid

• Erythematous discoloration

• Epidermophyton floccosum

• Trichophyton rubrum

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

• Long-term animal studies to determine the carcinogenic potential of Ecoza topical foam have not been performed.

• Oral administration of econazole nitrate in rats has been reported to produce prolonged anti- genic stimulation.

• 14 CLINICAL STUDIES

• In two multi-center, randomized, double-blind, vehicle-controlled clinical trials a total of 505 subjects with interdigital tinea pedis were randomized 1:1 to Ecoza topical foam; subjects applied the assigned medication once daily for 4 weeks. The severity of erythema, scaling, fissuring, maceration, vesiculation, and pruritus were graded using a 4-point scale (mild, moderate, severe). Subjects had KOH examination and fungal cultures taken immediately following application. A total of 338 subjects with positive fungal cultures were evaluated for efficacy. Efficacy was evaluated on Day 42, 2 weeks post-treatment with treatment success being defined as complete cure (negative KOH and fungal culture and no evidence of clinical disease). The study population ranged in age from 12 to 77 years with 5 subjects less than 18 years of age at baseline. The subjects were 71% male and 51% Caucasian. Table 1 presents the efficacy results for each trial.

Table 1: Efficacy Results at Two Weeks Post-treatment (Day 42) Complete Cure, Efficacious Treatment and Mycological Cure

<table>
<thead>
<tr>
<th></th>
<th>Complete cure</th>
<th>Efficacious treatment</th>
<th>Mycological cure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ecoza topical foam, 1%</td>
<td>19 (20.2%)</td>
<td>40 (48.8%)</td>
<td>16 (18.0%)</td>
</tr>
<tr>
<td>Foam Vehicle, M = 82 (N = 82)</td>
<td>2 (2.4%)</td>
<td>9 (10.5%)</td>
<td>13 (15.7%)</td>
</tr>
<tr>
<td>Ecoza topical foam, 1%</td>
<td>55 (62.8%)</td>
<td>44 (52.9%)</td>
<td>81 (95.1%)</td>
</tr>
<tr>
<td>Foam Vehicle, M = 82 (N = 82)</td>
<td>20 (23.5%)</td>
<td>46 (54.8%)</td>
<td>57 (67.5%)</td>
</tr>
</tbody>
</table>

• Clinical cure and/or mycological cure:

1. Clinical cure: Complete cure and/or mycological cure. (erythema, scaling, fissuring, maceration, vesiculation, or pruritus).

2. Mycological cure: and/or mycological cure: (fungus positive or negative, but no clinical signs and symptoms absent).

3. Negative KOH and fungal culture. (See Figures B and C)