ECONAZOLE NITRATE- econazole nitrate aerosol, foam
Trifluent Pharma, LLC

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use eonazole nitrate topical foam safely and effectively. See full prescribing information for econazole nitrate topical foam.

Econazole nitrate topical foam, 1%, for topical use

Initial U.S. Approval: 1982

INDICATIONS AND USAGE

Econazole nitrate 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. (1)

DOSAGE AND ADMINISTRATION

- For topical use only; not for oral, ophthalmic, or intravaginal use. (2)
- Apply once daily for 4 weeks. (2)

DOSAGE FORMS AND STRENGTHS

Foam, 1%. (3)

CONTRAINDICATIONS

None. (4)

WARNINGS AND PRECAUTIONS

Contents are flammable. Instruct the patient to avoid heat, flame, and/or smoking during and immediately following application. (5.1)

ADVERSE REACTIONS

During clinical trials with econazole nitrate topical foam, the most common adverse reactions were application site reactions which occurred in less than 1% of subjects in both the econazole nitrate and vehicle arms. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Trifluent Pharma at 1-800-927-5191 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.

Revised: 09/2025

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.

Revised: 9/2025

FULL PRESCRIBING INFORMATION: CONTENTS*

* Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

Econazole nitrate topical foam, 1%, is 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.

2 DOSAGE AND ADMINISTRATION

Econazole nitrate topical foam, 1% is for topical use only. Econazole nitrate topical foam, 1% is not for oral, ophthalmic, or intravaginal use.

Econazole nitrate topical foam, 1% should be applied to cover affected areas once daily for 4 weeks.

3 DOSAGE FORMS AND STRENGTHS

Foam, 1%. Each gram of econazole nitrate topical foam, 1%, contains 10 mg of econazole nitrate in a white to off-white foam.

4 CONTRAINDICATIONS

None.

5 WARNINGS AND PRECAUTIONS

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5.1 Flammability

Econazole nitrate 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.

6 ADVERSE REACTIONS

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6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

In two double-blind, vehicle-controlled clinical trials, 495 subjects were exposed to econazole nitrate topical foam or vehicle (246 subjects were exposed to econazole nitrate topical foam, 1% and 249 were exposed to vehicle). Subjects with interdigital tinea pedis applied foam or vehicle once daily for approximately 28 days. During clinical trials with econazole nitrate topical foam, the most common adverse reactions were application site reactions which occurred in less than 1% of subjects in both the econazole nitrate and vehicle arms.

7 DRUG INTERACTIONS

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7.1 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 Ratio (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.

8 USE IN SPECIFIC POPULATIONS

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8.1 Pregnancy

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Pregnancy Category C

There are no adequate and well-controlled trials with econazole nitrate topical foam in

pregnant women. Econazole nitrate topical foam should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Econazole nitrate has not been shown to be teratogenic when administered orally to mice, rabbits or rats. Fetotoxic or embryotoxic effects were observed in Segment I oral studies with rats receiving 10 to 40 times the human dermal dose. Similar effects were observed in Segment II or Segment III studies with mice, rabbits and/or rats receiving oral doses 80 or 40 times the human dermal dose.

8.3 Nursing Mothers

It is not known whether econazole nitrate is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when econazole nitrate is administered to a nursing woman. Following oral administration of econazole nitrate to lactating rats, econazole and/or metabolites were excreted in milk and were found in nursing pups.

8.4 Pediatric Use

Of the 173 subjects treated with econazole nitrate topical foam, 1% in the clinical trials, 2 subjects were 12 to 17 years old. In a pediatric maximal use trial, econazole nitrate topical foam, 1% was applied once daily to eighteen subjects aged 12 to 17 years with interdigital tinea pedis for 28 days [*see Clinical Pharmacology (12.3)*]. The safety findings for subjects 12 to 17 years were similar to those in adult population.

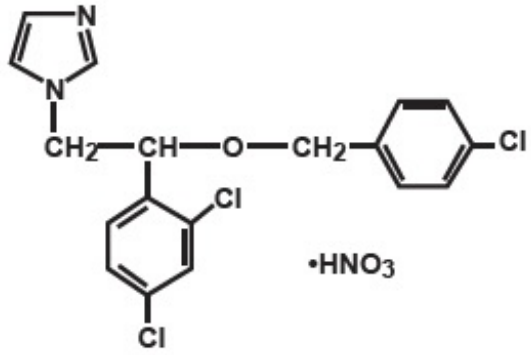
8.5 Geriatric Use

Of the 173 subjects treated with econazole nitrate topical foam, 1% in the adult clinical trials, 6 subjects were 65 years or older. No overall differences in safety or effectiveness were observed between these subjects and younger subjects.

11 DESCRIPTION

Econazole nitrate topical foam, 1% contains the azole antifungal agent, econazole nitrate in an oil-in-water emulsion base consisting of the following inactive ingredients: dimethicone, glycerin, polysorbate 20, povidone, propylene glycol, stearic acid, trolamine, purified water and butane as a propellant. Each gram of econazole nitrate topical foam, 1% contains 10 mg of econazole nitrate, USP, in a white to off-white foam. Econazola nitrate topical foam, 1% is alcohol (ethanol)-free and for topical use only.

Chemically, econazole nitrate is 1-[2-{(4-chloro-phenyl)methoxy}-2-(2,4-dichlorophenyl) ethyl]-1H-imidazole mononitrate. Econazole nitrate has the molecular formula $C_{18}H_{15}Cl_3N_2O$. $HNO_3$and a molecular weight of 444.70. Its molecular structure is as follows:



12 CLINICAL PHARMACOLOGY

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12.1 Mechanism of Action

Econazole nitrate topical foam is an azole antifungal [*see Clinical Pharmacology (12.4)*] **.**

12.2 Pharmacodynamics

The pharmacodynamics of econazole nitrate topical foam, 1% have not been established **.**

12.3 Pharmacokinetics

The systemic absorption of econazole nitrate topical foam, 1% following topical application was studied in one clinical trial in adults and one clinical study in pediatric subjects.

In the adult trial, 19 subjects (male and female) with tinea pedis applied econazole nitrate topical foam, 1% once daily for 29 days. Subjects applied a mean daily amount of 2.4 g of econazole nitrate topical foam, 1% to soles, toes, interdigital spaces and tops of both feet up to the ankles. Blood samples were obtained on Day 29 at pre-dose and 1, 2, 4, 6, 8, and 12 hours after application. Results (mean ± SD) showed the time to reach peak plasma concentrations (T_{max}) was 6.8 ± 5.1 h with maximum concentration (C_{max}) of 417 ± 218 pg/ml. The area under the concentration time curve for the first 12 hours post application on Day 29 ($AUC_{(0-12)}$) was 3440 ± 1920 pg-h/ml.

In the pediatric trial, 18 subjects (male and female ages 12 - 17) with interdigital tinea pedis and positive fungal cultures were treated with econazole nitrate topical foam, 1% once daily for 4 weeks. Subjects applied a mean daily amount of 3.2 g of econazole nitrate topical foam, 1% to soles, toes, interdigital spaces and tops of both feet up to the ankles. Blood samples were obtained on Day 28 at pre-dose and 7 h and 11 h post-dose. The mean ± SD econazole plasma concentration was 397 ± 289, 534 ± 745 and 575 ± 638 pg/mL at pre-dose and 7 h and 11 h post-dose, respectively.

12.4 Microbiology

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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 may be responsible for the fungistatic activity of econazole. Mammalian cell demethylation 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 (1)*].

Trichophyton rubrum

Epidermophyton floccosum

Trichophyton mentagrophytes

13 NONCLINICAL TOXICOLOGY

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13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

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

Oral administration of econazole nitrate in rats has been reported to produce prolonged gestation.

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 econazole nitrate topical foam or vehicle; 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 (none, mild, moderate, severe). Subjects had KOH examination and fungal cultures taken to confirm eligibility. A total of 339 subjects with positive fungal cultures were evaluated for efficacy. Efficacy was evaluated on Day 43, 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 71 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 43) Complete Cure, Effective Treatment and Mycological Cure

	Trial 1		**Trial 2**	
	Econazole Nitrate topical foam 1% N = 82 n(%)	**Foam Vehicle N = 83 n(%)**	**Econazole Nitrate topical foam, 1% N = 91 n(%)**	**Foam Vehicle N = 83 n(%)**

Complete cure [a]	19 (23.2%)	2 (2.4%)	23 (25.3%)	4 (4.8%)
Effective treatment [b]	40 (48.8%)	9 (10.8%)	44 (48.4%)	9 (10.8%)
Mycological cure [c]	56 (68.3%)	13 (15.7%)	61 (67.0%)	15 (18.1%)

[a]Mycological cure and an absence of clinical signs and symptoms (erythema, scaling, fissuring, maceration, vesiculation, or pruritus).
[b]Mycological cure and no or mild erythema and/or scaling with all other signs and symptoms absent.
[c]Negative KOH and fungal culture.

16 HOW SUPPLIED/ STORAGE AND HANDLING

Econazole nitrate topical foam, 1% is white to off-white foam supplied in 70g (NDC 73352-100-70) aluminum pressurized canister.

Store at controlled room temperature 20°C to 25°C (68°F to 77°F) with excursions permitted between 15°C and 30°C (59°F and 86°F). Do not refrigerate or freeze.

Econazole nitrate 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.

17 PATIENT COUNSELING INFORMATION

See FDA-approved patient labeling (Patient Information)

The patient should be instructed as follows:

- Inform patients that econazole nitrate topical foam, 1% is for topical use only. Econazole nitrate topical foam, 1% is not intended for oral, intravaginal, or ophthalmic use.
- Econazole nitrate 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 econazole nitrate topical foam, 1%, use of the medication should be discontinued.

Manufactured in the USA for

Trifluent Pharma, LLC
San Antonio TX 78213

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PRODERM TECHNOLOGY ®

U.S, Patent 5,993,830

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Issued: 9/2025

P/N 41384

Patient Information
Econazole nitrate topical foam, 1%

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

What is econazole nitrate topical foam?
Econazole nitrate 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 Econazole nitrate topical foam?
Before using econazole nitrate 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 econazole nitrate topical foam will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if econazole nitrate 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 econazole nitrate topical foam?
See the detailed Instructions for Usefor information about how to use econazole nitrate topical foam.

- Use econazole nitrate topical foam exactly as your doctor tells you to use it.
- Apply econazole nitrate topical foam to the affected skin areas of your feet 1 time a day for 4 weeks.
- If econazole nitrate topical foam gets in or near your eyes, rinse them well with water.
- Wash your hands after you apply econazole nitrate topical foam.

What should I avoid while using econazole nitrate topical foam?

- Econazole nitrate topical foam is flammable. Avoid heat, flame and smoking while applying and right after you apply econazole nitrate topical foam to your skin.

What are the possible side effects of econazole nitrate topical foam?
Econazole nitrate 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 econazole nitrate topical foam.
These are not all the possible side effects of econazole nitrate 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 store econazole nitrate topical foam?

- Store econazole nitrate topical foam at room temperature, between 68°F to 77°F (20°C to 25°C).
- Do not refrigerate or freeze econazole nitrate topical foam.

- Do not store econazole nitrate topical foam in direct sunlight.
- Econazole nitrate topical foam is flammable. Keep the econazole nitrate 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 econazole nitrate topical foam canister.

Keep econazole nitrate topical foam and all medicines out of the reach of children.

General information about the safe and effective use of econazole nitrate 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 econazole nitrate topical foam that is written for health professionals. Do not use econazole nitrate topical foam for a condition for which it was not prescribed. Do not give econazole nitrate topical foam to other people, even if they have the same symptoms that you have. It may harm them.

What are the ingredients in econazole nitrate topical foam?

Active ingredient:econazole nitrate USP

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

Manufactured for Trifluent Pharma, LLC, San Antonio, TX 78213 P/N 141384

For more information call Trifluent Pharma, LLC at 888927-5191

This Patient Information has been approved by the U.S. Food and Drug Administration.	Issued: 9.2025

Instructions for Use
Econazole Nitrate Topical Foam, 1%

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

Parts of econazole nitrate topical foam Canister. (See Figure A)

Figure A

How to apply econazole nitrate topical foam:

Step 1:	Before you apply econazole nitrate topical foam, shake the econazole nitrate topical foam canister for about 5 seconds.
Step 2:	Remove the cap and turn the econazole nitrate topical foam canister upside down over the palm of your hand.
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)**

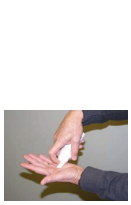

Figure B **Figure C**

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

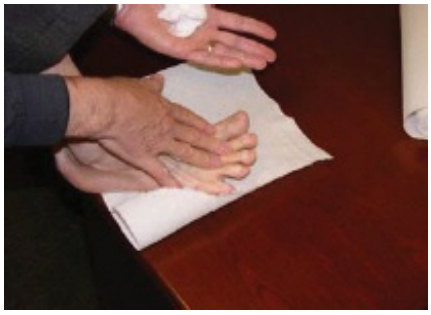

Figure D

Step 5: You should apply econazole nitrate 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 econazole nitrate topical foam.

How should I store econazole nitrate topical foam?

- Store econazole nitrate topical foam at room temperature, between 68°F to 77°F (20°C to 25°C).
- Do not refrigerate or freeze econazole nitrate topical foam.
- Do not store econazole nitrate topical foam in direct sunlight.
- Econazole nitrate topical foam is flammable. Keep the econazole nitrate 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 econazole nitrate topical foam canister.

Keep econazole nitrate 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 for Trifluent Pharma, LLC, San Antonio, TX 78213

Issued: 09/2025

PRINCIPAL DISPLAY PANEL - 70 g Canister Label

NDC 73352-100-70

Econazole nitrate topical foam, 1%

For Topical Use Only

Not for ophthalmic, oral or intravaginal use.

Keep Out of Reach of Children

Rx Only
Net Wt 70g

ECONAZOLE NITRATE

econazole nitrate aerosol, foam

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:73352-100
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ECONAZOLE NITRATE (UNII: H438WYN10E) (ECONAZOLE - UNII:6Z1Y2V4A7M)	ECONAZOLE NITRATE	10 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
DIMETHICONE (UNII: 92RU3N3Y1O)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
POVIDONE K30 (UNII: U725QWY32X)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

STEARIC ACID (UNII: 4ELV7Z65AP)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	
BUTANE (UNII: 6LV4FOR43R)	

Product Characteristics

Color	white (white to off-white)	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73352-100-70	1 in 1 CARTON	09/13/2025	
1		70 g in 1 CANISTER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA205175	09/13/2025	

Labeler - Trifluent Pharma, LLC (117167281)

Revised: 9/2025 Trifluent Pharma, LLC