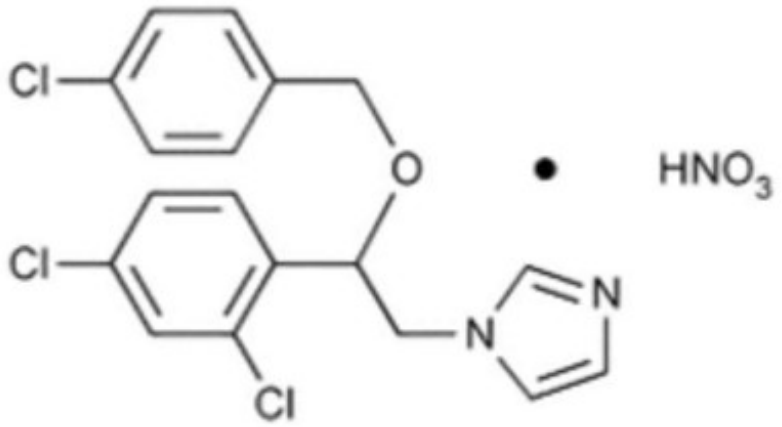
ECONAZOLE NITRATE- econazole nitrate cream
SOLA Pharmaceuticals

Econazole Nitrate

Description

Econazole Nitrate Cream 1% contains the antifungal agent, econazole nitrate 1% in a water miscible base consisting of pegoxol 7 stearate, peglicol 5 oleate, mineral oil, benzoic acid, butylated hydroxyanisole, and purified water. The white to off-white soft cream is for topical use only.

Chemically, econazole nitrate is 1-[2-{(4-chloro-phenyl) methoxy}-2-(2,4-dichlorophenyl)ethyl]-1H-imidazole mononitrate. Its structure is as follows:



Clinical Pharmacology

After topical application to the skin of normal subjects, systemic absorption of econazole nitrate is extremely low. Although most of the applied drug remains on the skin surface, drug concentrations were found in the stratum corneum which, by far, exceeded the minimum inhibitory concentration for dermatophytes. Inhibitory concentrations were achieved in the epidermis and as deep as the middle region of the dermis. Less than 1% of the applied dose was recovered in the urine and feces.

Microbiology

Econazole nitrate has been shown to be active against most strains of the following microorganisms, both in vitro and in clinical infections as described in the INDICATIONS AND USAGE section.

Dermatophytes	Yeasts
Epidermophyton floccosum	*Candida albicans*
Microsporum audouini	*Malassezia furfur*
Microsporum canis	
Microsporum gypseum	
Trichophyton mentagrophytes	
Trichophyton rubrum	
Trichophyton tonsurans	

Econazole nitrate exhibits broad-spectrum antifungal activity against the following organisms *in vitro*, **but the clinical significance of these data is unknown.**

Dermatophytes	Yeasts
Trichophyton verrucosum	*Candida guillermondii*
	Candida parapsilosis
	Candida tropicalis

Indication and Usage

ECONAZOLE NITRATE CREAM 1% is indicated for topical application in the treatment of tinea pedis, tinea cruris, and tinea corporis caused by Trichophyton rubrum, Trichophyton mentagrophytes, **Trichophyton tonsurans, Microsporum canis, Microsporum audouini, Microsporum gypseum, and Epidermophyton floccosum**, in the treatment of cutaneous candidiasis, and in the treatment of tinea versicolor.

Contraindications

ECONAZOLE NITRATE CREAM 1% is contraindicated in individuals who have shown hypersensitivity to any of its ingredients.

Warnings

ECONAZOLE NITRATE CREAM 1% is not for ophthalmic use.

Precautions

General

If a reaction suggesting sensitivity or chemical irritation should occur, use of the medication should be discontinued.

For external use only.

Avoid introduction of ECONAZOLE NITRATE CREAM 1% into the eyes.

Carcinogenicity Studies
Long-term animal studies to determine carcinogenic potential have not been performed.

Fertility (Reproduction)
Oral administration of econazole nitrate in rats has been reported to produce prolonged gestation. Intravaginal administration in humans has not shown prolonged gestation or other adverse reproductive effects attributable to econazole nitrate therapy.

Pregnancy
Pregnancy Category C
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. Econazole nitrate should be used in the first trimester of pregnancy only when the physician considers it essential to the welfare of the patient. The drug should be used during the second and third trimesters of pregnancy only if clearly needed.

Nursing Mothers
It is not known whether econazole nitrate is excreted in human milk. Following oral administration of econazole nitrate to lactating rats, econazole and/or metabolites were excreted in milk and were found in nursing pups. Also, in lactating rats receiving large oral doses (40 or 80 times the human dermal dose), there was a reduction in post partum viability of pups and survival to weaning; however, at these high doses, maternal toxicity was present and may have been a contributing factor. Caution should be exercised when econazole nitrate is administered to a nursing woman.

Adverse Reactions

During clinical trials, approximately 3% of patients treated with econazole nitrate 1% cream reported side effects thought possibly to be due to the drug, consisting mainly of burning, itching, stinging, and erythema. One case of pruritic rash has also been reported.

To report **SUSPECTED ADVERSE REACTIONS**, contact Teligent Pharma, Inc. at 1-856-697-1441, or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Overdose

Overdosage of econazole nitrate in humans has not been reported to date. In mice, rats, guinea pigs and dogs, the oral LD50 values were found to be 462, 668, 272, and >160 mg/kg, respectively.

Dosage and Administration

Sufficient ECONAZOLE NITRATE CREAM 1% should be applied to cover affected areas once daily in patients with tinea pedis, tinea cruris, tinea corporis, and tinea versicolor, and twice daily (morning and evening) in patients with cutaneous candidiasis. Early relief of symptoms is experienced by the majority of patients and clinical improvement may be seen fairly soon after treatment is begun; however, candidal infections and tinea cruris and corporis should be treated for two weeks and tinea pedis for one month in order to reduce the possibility of recurrence. If a patient shows no clinical improvement after the treatment period, the diagnosis should be redetermined. Patients with tinea versicolor usually exhibit clinical and mycological clearing after two weeks of treatment.

How Supplied

ECONAZOLE NITRATE CREAM 1% is supplied in tubes of 30 grams (NDC 70512-029-30), and 85 grams (NDC 70512-029-85).

Store at controlled room temperature 20° - 25°C (68° - 77°F).

Manufactured for

Sola Pharmaceuticals

Baton Rouge, LA 70809

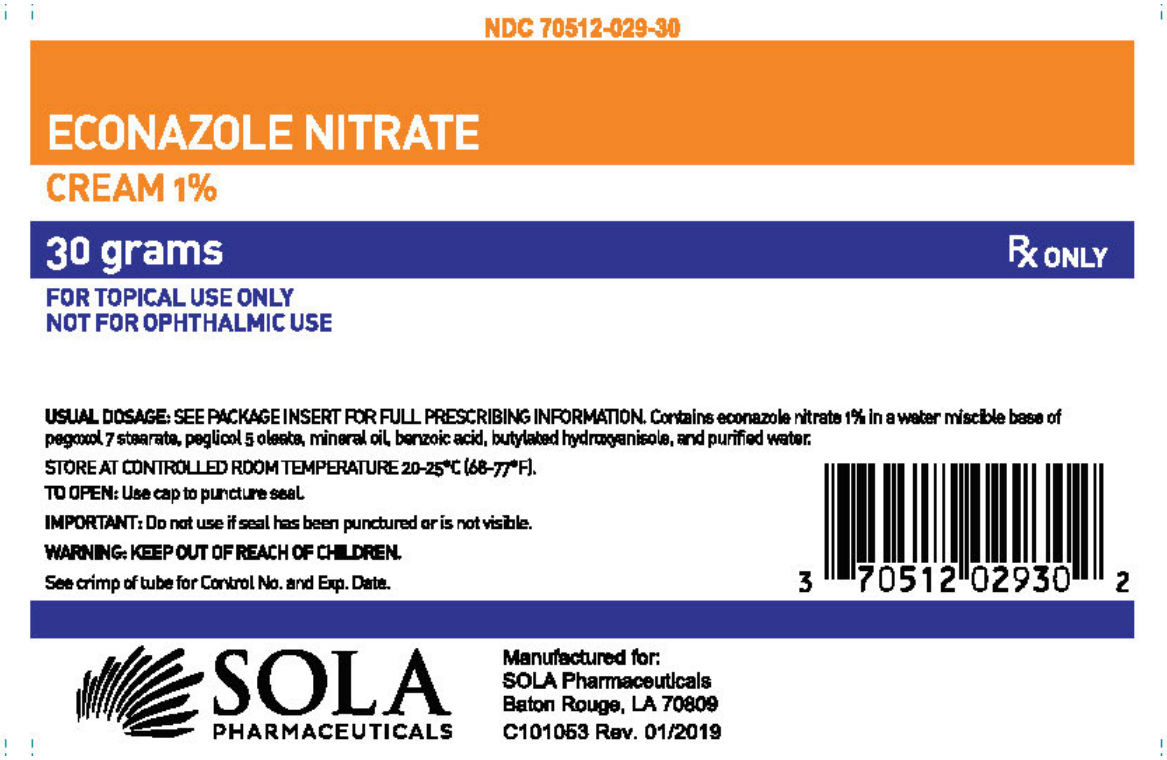
Rev. 01/2019

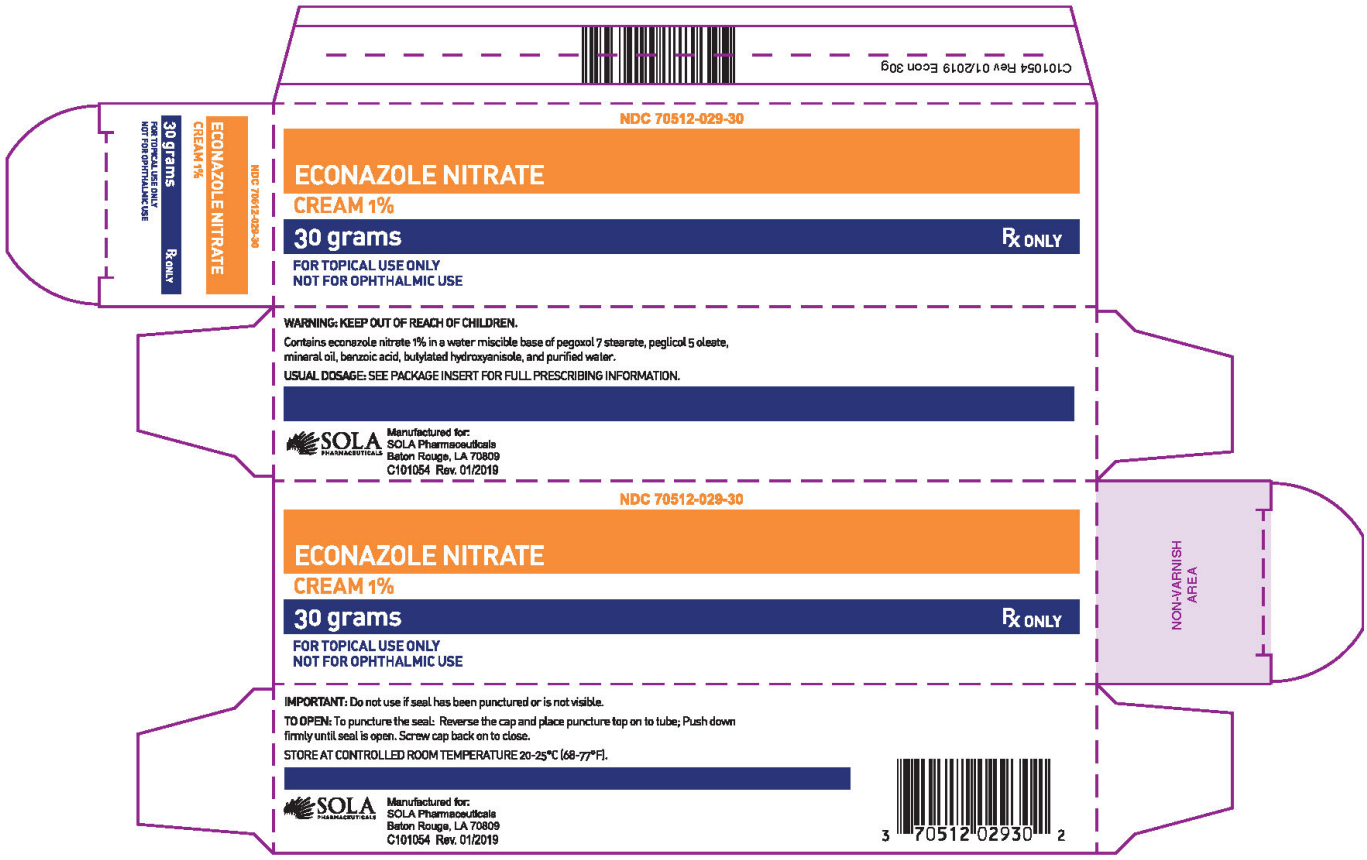
Principal Display Panel

30g Tube NDC 70512-029-30

85g Tube NDC 70512-029-85

ECONAZOLE NITRATE CREAM 1%





NDC 70512-029-85

ECONAZOLE NITRATE

CREAM 1%

85 grams Rx ONLY

FOR TOPICAL USE ONLY
NOT FOR OPHTHALMIC USE

USUAL DOSAGE: SEE PACKAGE INSERT FOR FULL PRESCRIBING INFORMATION. Contains econazole nitrate 1% in a water miscible base of pegoxol 7 stearate, peglicol 5 oleate, mineral oil, benzoic acid, butylated hydroxyanisole, and purified water.

STORE AT CONTROLLED ROOM TEMPERATURE 20-25°C (68-77°F).

TO OPEN: Use cap to puncture seal.

IMPORTANT: Do not use if seal has been punctured or is not visible.

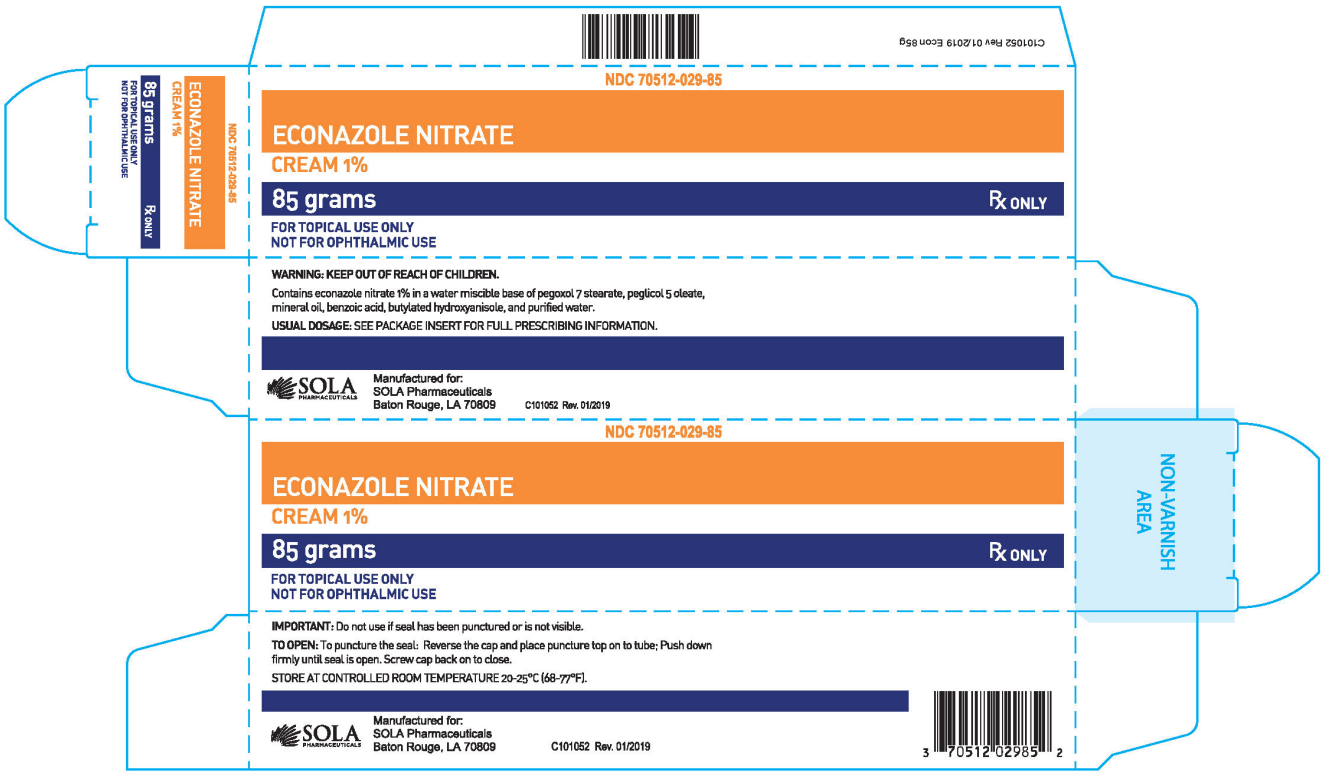
WARNING: KEEP OUT OF REACH OF CHILDREN.

See crimp of tube for Control No. and Exp. Date.

3 70512 02985 2

SOLA PHARMACEUTICALS

Manufactured for:
SOLA Pharmaceuticals
Baton Rouge, LA 70809
C101051 Rev. 01/2019



ECONAZOLE NITRATE

econazole nitrate cream

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70512-029
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**
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
MINERAL OIL (UNII: T5L8T28FGP)	
WATER (UNII: 059QF0KO0R)	
PEG-5 OLEATE (UNII: 0240V77G50)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
PEGOXOL 7 STEARATE (UNII: 3EW5AXE5X5)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70512-029-85	1 in 1 CARTON	02/04/2019	
1		85 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:70512-029-30	1 in 1 CARTON	02/04/2019	
2		30 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076574	02/04/2019	

Labeler - SOLA Pharmaceuticals (080121345)

Revised: 9/2019 SOLA Pharmaceuticals