CICLOPIROX- ciclopirox lotion
E. Fougera & Co. a division of Fougera Pharmaceuticals Inc.

CICLOPIROX TOPICAL SUSPENSION USP,
0.77% (w/w) (LOTION)

Rx only
FOR DERMATOLOGIC USE ONLY
NOT FOR OPHTHALMIC USE

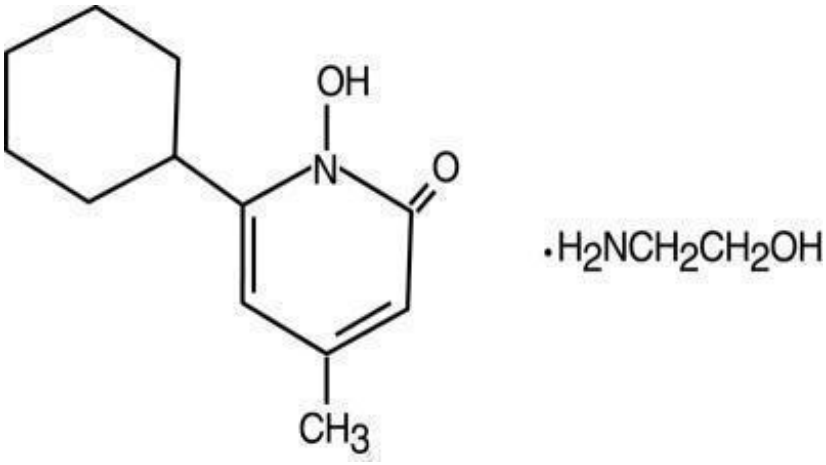
DESCRIPTION:

Ciclopirox Topical Suspension USP, 0.77% (Lotion) is for topical use.

Each gram of Ciclopirox Topical Suspension USP, 0.77% (Lotion) contains 7.7 mg of ciclopirox (as ciclopirox olamine) in a water miscible lotion base consisting of purified water USP, cocamide DEA, octyldodecanol NF, mineral oil USP, stearyl alcohol NF, cetyl alcohol NF, polysorbate 60 NF, myristyl alcohol NF, sorbitan monostearate NF, lactic acid USP, and benzyl alcohol NF (1%) as a preservative.

Ciclopirox Topical Suspension USP, 0.77% (Lotion) contains a synthetic, broad-spectrum, antifungal agent ciclopirox (as ciclopirox olamine). The chemical name is 6-cyclohexyl-1-hydroxy-4-methyl-2(1*H*)-pyridone, 2-aminoethanol salt.

The CAS Registry Number is 41621-49-2. The chemical structure is:



Ciclopirox Topical Suspension USP, 0.77% (Lotion) has a pH of 7.

CLINICAL PHARMACOLOGY:

Ciclopirox is a broad-spectrum, antifungal agent that inhibits the growth of pathogenic dermatophytes, yeasts, and *Malassezia furfur*. Ciclopirox exhibits fungicidal activity *in vitro* against isolates of *Trichophyton rubrum*, *Trichophyton mentagrophytes*, *Epidermophyton floccosum*, *Microsporum canis*, and *Candida albicans*.

Pharmacokinetic studies in men with radiolabeled ciclopirox solution in polyethylene glycol 400, showed an average of 1.3% absorption of the dose when it was applied topically to 750 cm^2 on the back followed by occlusion for 6 hours. The biological half-life was 1.7 hours and excretion occurred via the kidney. Two days after application only 0.01% of the dose applied could be found in the urine. Fecal excretion was negligible. Autoradiographic studies with human cadaver skin showed that

ciclopirox penetrates into the hair and through the epidermis and hair follicles into the sebaceous glands and dermis, while a portion of the drug remains in the stratum corneum.

In vitro penetration studies in frozen or fresh excised human cadaver and pig skin indicated that the penetration of Ciclopirox Topical Suspension USP, 0.77% (Lotion) is equivalent to that of Ciclopirox Cream 0.77%. Therapeutic equivalence of cream and lotion formulations also was indicated by studies of experimentally induced guinea pig and human trichophytosis.

INDICATIONS AND USAGE:

Ciclopirox Topical Suspension USP, 0.77% (Lotion) is indicated for the topical treatment of the following dermal infections: tinea pedis, tinea cruris, and tinea corporis due to *Trichophyton rubrum*, *Trichophyton mentagrophytes*, *Epidermophyton floccosum*, and *Microsporum canis*; cutaneous candidiasis (moniliasis) due to *Candida albicans*; and tinea (pityriasis) versicolor due to *Malassezia furfur*.

CONTRAINDICATIONS:

Ciclopirox Topical Suspension USP, 0.77% (Lotion) is contraindicated in individuals who have shown hypersensitivity to any of its components.

WARNINGS:

General: Ciclopirox Topical Suspension USP, 0.77% (Lotion) is not for ophthalmic use.

Keep out of reach of children.

PRECAUTIONS:

If a reaction suggesting sensitivity or chemical irritation should occur with the use of Ciclopirox Topical Suspension USP, 0.77% (Lotion), treatment should be discontinued and appropriate therapy instituted.

Information for Patients

The patient should be told to:

1. Use the medication for the full treatment time even though signs/symptoms may have improved and notify the physician if there is no improvement after four weeks.
2. Inform the physician if the area of application shows signs of increased irritation (redness, itching, burning, blistering, swelling, oozing) indicative of possible sensitization.
3. Avoid the use of occlusive wrappings or dressings.

Carcinogenesis, Mutagenesis, Impairment of Fertility: A carcinogenicity study in female mice dosed cutaneously twice per week for 50 weeks followed by a 6-month drug free observation period prior to necropsy revealed no evidence of tumors at the application site. The following *in vitro* and *in vivo* genotoxicity tests have been conducted with ciclopirox olamine: studies to evaluate gene mutation in the Ames *Salmonella I* Mammalian Microsome Assay (negative) and Yeast Saccharomyces Cerevisiae Assay (negative); and studies to evaluate chromosome aberrations *in vivo* in the Mouse Dominant Lethal Assay, and in the Mouse Micronucleus Assay at 500 mg/kg (negative). The following battery of *in vitro* genotoxicity tests were conducted with ciclopirox: a chromosome aberration assay in V79 Chinese Hamster Cells, with and without metabolic activation (positive); a gene mutation assay in the HGPRT - test with V79 Chinese Hamster Cells (negative); and a primary DNA damage assay (i.e., unscheduled DNA Synthesis Assay in A549 Human Cells (negative)). An *in vitro* Cell Transformation Assay in BALB/C3T3 Cells was negative for cell transformation. In an *in vivo* Chinese Hamster Bone Marrow

Cytogenetic Assay, ciclopirox was negative for chromosome aberrations at 5000 mg/kg.

Pregnancy Category B. Reproduction studies have been performed in the mouse, rat, rabbit, and monkey, via various routes of administration, at doses 10 times or more the topical human dose and have revealed no significant evidence of impaired fertility or harm to the fetus due to ciclopirox. There are, however, no adequate or well controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Caution should be exercised when Ciclopirox Topical Suspension USP, 0.77% (Lotion) is administered to a nursing woman.

Pediatric Use: Safety and effectiveness in pediatric patients below the age of 10 years have not been established.

ADVERSE REACTIONS:

In the controlled clinical trial with 89 patients using Ciclopirox Topical Suspension USP, 0.77% (Lotion) and 89 patients using the lotion vehicle, the incidence of adverse reactions was low. Those considered possibly related to treatment or occurring in more than one patient were pruritus, which occurred in two patients using Ciclopirox Topical Suspension USP, 0.77% (Lotion) and one patient using the lotion vehicle; and burning, which occurred in one patient using Ciclopirox Topical Suspension USP, 0.77% (Lotion).

DOSAGE AND ADMINISTRATION:

Gently massage Ciclopirox Topical Suspension USP, 0.77% (Lotion) into the affected and surrounding skin areas twice daily, in the morning and evening. Clinical improvement with relief of pruritus and other symptoms usually occurs within the first week of treatment. If a patient shows no clinical improvement after four weeks of treatment with Ciclopirox Topical Suspension USP, 0.77% (Lotion) the diagnosis should be redetermined. Patients with tinea versicolor usually exhibit clinical and mycological clearing after two weeks of treatment.

HOW SUPPLIED:

Ciclopirox Topical Suspension USP, 0.77% (Lotion) is supplied in:

30 mL bottles (**NDC** 0168-0314-30)
60 mL bottles (**NDC** 0168-0314-60)

Bottle space provided to allow for vigorous shaking before each use.
Store between 5°-25°C (41°-77°F).

E. FOUGERA & CO.
A division of
Fougera
PHARMACEUTICAL INC.
Melville, New York 11747

I2314C/IF2314C
R08/14
#218

PACKAGE LABEL – PRINCIPAL DISPLAY PANEL – 30 ML CONTAINER

NDC 0168-0314-30

Fougera®

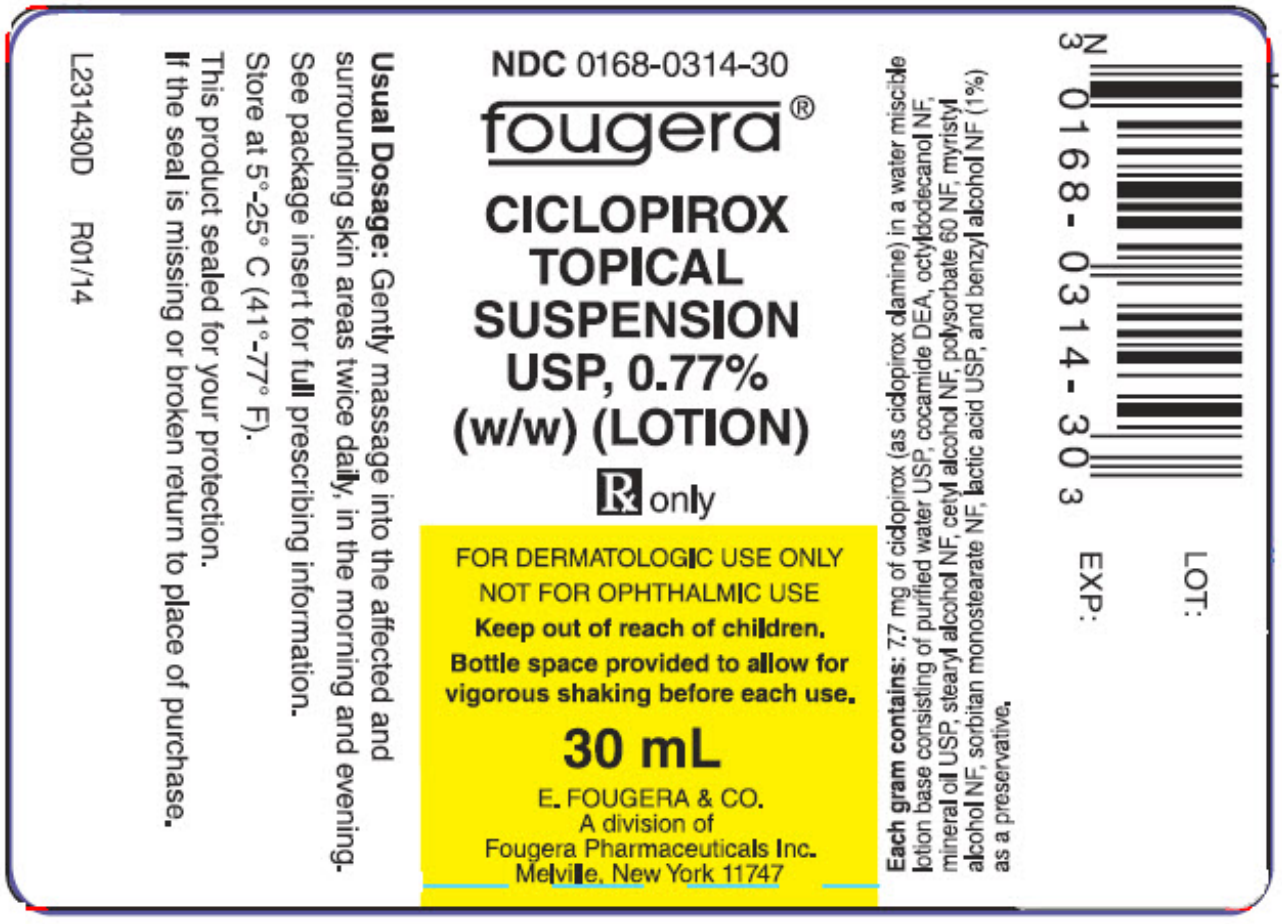
CICLOPIROX
TOPICAL
SUSPENSION
USP 0.77%
(w/w) (LOTION)

Rx Only

FOR DERMATOLOGIC USE ONLY
NOT FOR OPHTHALMIC USE

Keep out of reach of children.
Bottle space provided to allow for vigorous shaking before each use.

30 mL



PACKAGE LABEL – PRINCIPAL DISPLAY PANEL – 30 ML CARTON

NDC 0168-0314-30

Fougera®

CICLOPIROX
TOPICAL
SUSPENSION,

USP 0.77%
(w/w) (LOTION)

Rx Only

FOR DERMATOLOGIC
USE ONLY
NOT FOR OPHTHALMIC USE

Keep out of reach
of children.

Bottle space provided to
allow for vigorous shaking
before each use.

30 mL

CICLOPIROX

ciclopirox lotion

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0168-0314
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CICLOPIROX OLAMINE (UNII: 50MD4SB4AP) (CICLOPIROX - UNII:19W019ZDRJ)	CICLOPIROX	7.7 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
COCO DIETHANOLAMIDE (UNII: 92005F972D)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
MINERAL OIL (UNII: T5L8T28FGP)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
MYRISTYL ALCOHOL (UNII: V42034O9PU)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	
LACTIC ACID (UNII: 33X04XA5AT)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0168-0314-30	30 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:0168-0314-60	60 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076422	08/06/2004	

Labeler - E. Fougera & Co. a division of Fougera Pharmaceuticals Inc. (043838424)

Revised: 8/2014 E. Fougera & Co. a division of Fougera Pharmaceuticals Inc.