CICLOPIROX OLAMINE - ciclopirox olamine cream
Lake Erie Medical DBA Quality Care Products LLC

Ciclopirox Olamine 15g Cream

DESCRIPTION

Ciclopirox olamine cream, USP is for topical use.

Each gram of ciclopirox olamine cream, USP contains 7.70 mg of ciclopirox (as Ciclopirox Olamine) in a water miscible vanishing cream base consisting of Purified Water USP, Octyldodecanol NF, Light Mineral Oil NF, Stearyl Alcohol NF, Cetyl Alcohol NF, Polysorbate 60 NF, Myristyl Alcohol NF, Sorbitan Monostearate NF, Lactic Acid USP, and Benzyl Alcohol NF (1%) as preservative.

Ciclopirox olamine cream, USP 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 olamine cream, USP 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, Epidermorphyton floccosum, Microsporum canis, and Candida albicans.*

Pharmacokinetic studies in men with tagged 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.

Penetration studies in human cadaverous skin from the back, with ciclopirox olamine cream, USP with tagged ciclopirox showed the presence of 0.8 to 1.6% of the dose in the stratum corneum 1.5 to 6 hours after application. The levels in the dermis were still 10 to 15 times above the minimum inhibitory concentrations.

Autoradiographic studies with human cadaverous 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.

Draize Human Sensitization Assay, 21-Day Cumulative Irritancy study, Phototoxicity study, and Photo-Draize study conducted in a total of 142 healthy subjects showed no contact sensitization of the delayed hypersensitivity type, no irritation, no phototoxicity, and no photo-contact sensitization due to ciclopirox olamine cream, USP.

INDICATIONS AND USAGE

Ciclopirox olamine cream, USP 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;* candidiasis *(moniliasis)* due to *Candida albicans;* and tinea (pityriasis) versicolor due to *Malassezia furfur.*

CONTRAINDICATIONS

Ciclopirox olamine cream, USP is contraindicated in individuals who have shown hypersensitivity to any of its components.

WARNINGS

Ciclopirox olamine cream, USP 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 olamine cream, USP, treatment should be discontinued and appropriate therapy instituted.

ADVERSE REACTIONS

In all controlled clinical studies with 514 patients using ciclopirox olamine cream, USP and in 296 patients using the vehicle cream, the incidence of adverse reactions was low. This included pruritus at the site of application in one patient and worsening of the clinical signs and symptoms in another patient using ciclopirox olamine cream, USP and burning in one patient and worsening of the clinical signs and symptoms in another patient using the vehicle cream.

DOSAGE AND ADMINISTRATION

Gently massage ciclopirox olamine cream, USP 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 olamine cream, USP the diagnosis should be redetermined. Patients with tinea versicolor usually exhibit clinical and mycological clearing after two weeks of treatment.

HOW SUPPLIED

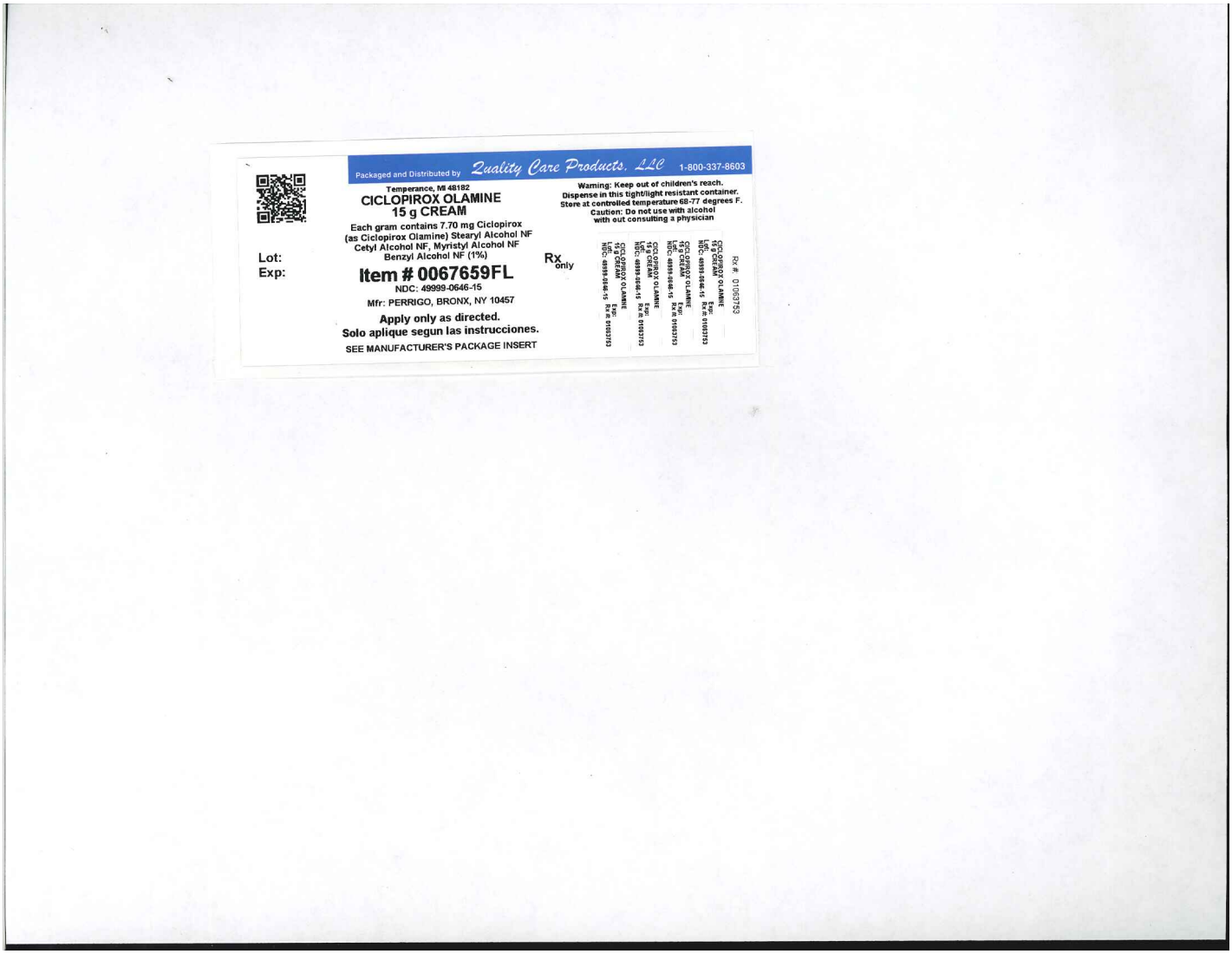
Ciclopirox olamine cream, USP is supplied in 15 gram, 30 gram, and 90 gram tubes.

Information for Patients

The patient should be told to:

1. Use the medication for the full treatment time even though 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, or oozing) indicative of possible sensitization.
3. Avoid the use of occlusive wrappings or dressings.

Image of label



CICLOPIROX OLAMINE

ciclopirox olamine cream

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:49999-646(NDC:45802-138)
Route of Administration	TOPICAL		

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

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
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:49999-646-15	15 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077364	11/03/2010	

Labeler - Lake Erie Medical DBA Quality Care Products LLC (831276758)

Establishment

Name	Address	ID/FEI	Business Operations
Lake Erie Medical DBA Quality Care Products LLC		831276758	relabel

Establishment

Name	Address	ID/FEI	Business Operations
L.Perrigo Company		006013346	manufacture

Revised: 11/2010 Lake Erie Medical DBA Quality Care Products LLC