

**CICLOPIROX OLAMINE- ciclopirox olamine cream**  
**Dispensing Solutions, Inc.**

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**Ciclopirox Olamine Cream USP, 0.77%**

**FOR DERMATOLOGIC USE ONLY.**  
**NOT FOR USE IN EYES.**

**DESCRIPTION**

Ciclopirox olamine cream USP, 0.77% is for topical use. Each gram of ciclopirox olamine cream USP contains 7.70 mg of ciclopirox (as ciclopirox olamine USP) in a water miscible vanishing cream base consisting of purified water USP, cetyl alcohol NF, light mineral oil NF, octyldodecanol NF, stearyl 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 USP). 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:

**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 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<sup>2</sup> 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 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 concentration.

Autoradiographic studies with human cadaverous skin showed that ciclopirox penetrated 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 male subjects showed no contact sensitization of the delayed hypersensitivity type, no irritation, no phototoxicity, and no photo-contact sensitization due to

ciclopirox olamine cream.

## INDICATIONS AND USAGE

Ciclopirox olamine cream 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) vesicolor due to *Malassezia furfur*.

## CONTRAINDICATIONS

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

## WARNINGS

Ciclopirox olamine cream is not for ophthalmic use.

**Keep out of the reach of children.**

## PRECAUTIONS

If a reaction suggesting sensitivity or chemical irritation should occur with the use of ciclopirox olamine cream, 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 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.

### 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*/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 5,000 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 woman. 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. Because many drugs are excreted in human milk, caution should be exercised when ciclopirox olamine cream 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 all controlled clinical studies with 514 patients using ciclopirox olamine cream 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 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 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, 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, 0.77% is supplied in 15 gram (NDC 68462-297-17), 30 gram (NDC 68462-297-35) and 90 gram (NDC 68462-297-92) tubes.

Store at 20-25°C (68-77°F) [see USP Controlled Room Temperature].

Manufactured by:

**Glenmark Generics Ltd.**

Colvale-Bardez, Goa 403 513, India

Manufactured for:



**Glenmark Generics Inc., USA**

Mahwah, NJ 07430

Questions? 1 (888)721-7115

[www.glenmarkgenerics.com](http://www.glenmarkgenerics.com)

February 2011

## **PRINCIPAL DISPLAY PANEL**

BULK SOURCE DATA  
 MFD. FOR: GLENMARK GENERICS  
 INC., USA  
 MAHWAH, NJ 07430

**PRODUCT ID:**  
 RED / WHITE / BLACK BOX  
 PRINTED NDC 68462-297-35

**BULK SOURCE NDC: 68462-0297-35**  
 MFR. LOT: XXXXXX  
 PEDIGREE #: 20514216  
 DISPENSE IN THIS  
 TIGHT/LIGHT RESISTANT CONTAINER



GENTLY MASSAGE INTO THE  
 AFFECTED AND SURROUNDING  
 SKIN AREA(S) TWICE DAILY IN  
 THE MORNING AND EVENING.  
 FOR DERMATOLOGIC USE ONLY.  
 NOT FOR USE IN EYES.



WARNING: KEEP OUT OF  
 CHILDREN'S REACH  
 STORE AT 68°- 77°F. SEE USP.

3C0526 NDC 68258-3996-03  
 CICLOPIROX OLAMINE 0.77%  
 30 g CREAM  
 LOT # SAMPLE EXP: 00-00  
 MN 68462-0297-35 RX# 25895355

3C0526 NDC 68258-3996-03  
 CICLOPIROX OLAMINE 0.77%  
 30 g CREAM  
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 MN 68462-0297-35 RX# 25895355

3C0526 NDC 68258-3996-03  
 CICLOPIROX OLAMINE 0.77%  
 30 g CREAM  
 LOT # SAMPLE EXP: 00-00  
 MN 68462-0297-35 RX# 25895355



Packaged Exclusively By:  
 DISPENSING  
 SOLUTIONS Inc.  
 Santa Ana, CA 92704

## CICLOPIROX OLAMINE 0.77%

**30 g CREAM**

**NDC 68258-3996-03  
 PRODUCT # 3C0526**

EACH GRAM CONTAINS:  
 7.70 mg OF CICLOPIROX  
 (AS CICLOPIROX OLAMINE USP)  
 IN A WATER MISCIBLE  
 VANISHING CREAM BASE

LOT# SAMPLE EXP: 00-00 Rx # 25895355

**RX ONLY**

Rev. Date: 01/12

NDC 68258-3996-03

## CICLOPIROX OLAMINE

ciclopirox olamine cream

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:68258-3996(NDC:68462-297)
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
CETYL ALCOHOL (UNII: 936JST6JCN)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
OCTYLDODECANOL (UNII: 461N10614Y)	
STEARYL ALCOHOL (UNII: 2KR89I4HIY)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
MYRISTYL ALCOHOL (UNII: V42034O9PU)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	
LACTIC ACID (UNII: 33X04XA5AT)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
WATER (UNII: 059QF0K00R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:68258-3996-3	30 g in 1 CARTON		
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
ANDA	ANDA090273	11/13/2009		

**Labeler** - Dispensing Solutions, Inc. (066070785)

**Registrant** - PSS World Medical, Inc. (101822682)

**Establishment**

Name	Address	ID/FEI	Business Operations
Dispensing Solutions, Inc.		066070785	relabel(68258-3996) , repack(68258-3996)

Revised: 10/2012

Dispensing Solutions, Inc.