CICLOPIROX OLAMINE- ciclopirox olamine suspension
Bryant Ranch Prepack

Ciclopirox Olamine Topical Suspension USP, 0.77% (w/w) (Lotion)
Rx Only

FOR DERMATOLOGIC USE ONLY.

NOT FOR USE IN EYES.

DESCRIPTION

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

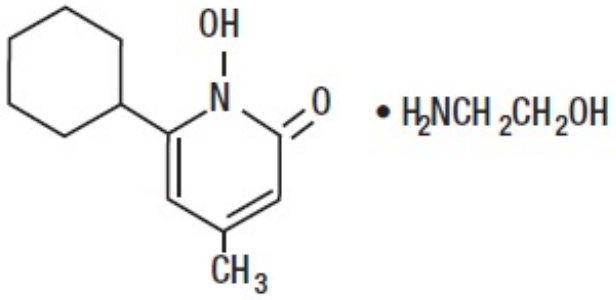
Each gram of Ciclopirox Olamine Topical Suspension USP, 0.77% (w/w) (Lotion) contains 7.70 mg of ciclopirox (as ciclopirox olamine) in a water miscible suspension base consisting of benzyl alcohol (1% as a preservative), cetyl alcohol, lactic acid, light mineral oil, myristyl alcohol, octyldodecanol, polysorbate 60, purified water, sorbitan monostearate, and stearyl alcohol.

Ciclopirox Olamine Topical Suspension USP, 0.77% (w/w) (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.

Ciclopirox Olamine Topical Suspension USP, 0.77% (w/w) (Lotion) has a pH of 7. 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 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 olamine topical suspension, 0.77% is equivalent to that of ciclopirox (ciclopirox olamine) cream 0.77%. Therapeutic equivalence of cream and suspension formulations was also indicated by studies of experimentally induced guinea pig and human trichophytosis.

INDICATIONS AND USAGE

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

WARNINGS

General -

Ciclopirox Olamine Topical Suspension USP, 0.77% (w/w) (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 Olamine Topical Suspension USP, 0.77% (w/w) (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*/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 Olamine Topical Suspension USP, 0.77% (w/w) (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 olamine topical suspension and 89 patients using the 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 olamine topical suspension and one patient using the suspension vehicle, and burning, which occurred in one patient

using ciclopirox olamine topical suspension.

DOSAGE AND ADMINISTRATION

Gently massage Ciclopirox Olamine Topical Suspension USP, 0.77% (w/w) (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 Olamine Topical Suspension USP, 0.77% (w/w) (Lotion) the diagnosis should be redetermined. Patients with tinea versicolor usually exhibit clinical and mycological clearing after two weeks of treatment.

HOW SUPPLIED

Ciclopirox Olamine Topical Suspension USP, 0.77% (w/w) (Lotion) is available as follow:

NDC: 72162-1406-3: 30 mL in a BOTTLE

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

Repackaged/Relabeled by:

Bryant Ranch Prepack, Inc.

Burbank, CA 91504

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

Manufactured By Padagis

Yeruham, Israel

Distributed By

Padagis

Allegan, MI 49010 • www.padagis.com

Rev 01-22

98L00 RC J1

Ciclopirox Olamine 0.77% Lotion, USP 30 mL

Each gram contains: 7.70 mg of ciclopirox (as ciclopirox olamine) in a water miscible vanishing suspension base consisting of benzyl alcohol (1% as a preservative), cetyl alcohol, lactic acid, light mineral oil, myristyl alcohol, octyldodecanol, polysorbate 60, purified water, sorbitan monostearate, and stearyl alcohol.

Keep this and all medication out of the reach of children.

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

For dermatologic use only.

NOT FOR OPHTHALMIC USE.

NDC 72162-**1406**-3

Ciclopirox Olamine Topical Suspension, USP (w/w)(Lotion)

0.77%

BRP PHARMACEUTICALS

Rx only

30 mL

Relabeled by:
Bryant Ranch Prepack, Inc.
Burbank, CA 91504 USA

Manufactured by:
Padagis

CICLOPIROX OLAMINE

ciclopirox olamine suspension

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:72162-1406(NDC:45802-400)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CICLOPIROX OLAMINE (UNII: 50MD4SB4AP) (CICLOPIROX - UNII:19W019ZDRJ)	CICLOPIROX	7.70 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
LACTIC ACID, UNSPECIFIED FORM (UNII: 33X04XA5AT)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
MYRISTYL ALCOHOL (UNII: V42034O9PU)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
WATER (UNII: 059QF0KO0R)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1	NDC:72162-1406-3	1 in 1 CARTON	10/02/2023	
1		30 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	ANDA077676	12/29/2006	

Labeler - Bryant Ranch Prepack (171714327)

Registrant - Bryant Ranch Prepack (171714327)

Establishment

Name	Address	ID/FEI	Business Operations
Bryant Ranch Prepack		171714327	REPACK(72162-1406) , RELABEL(72162-1406)

Revised: 10/2023 Bryant Ranch Prepack