

LOPROX[®] Lotion
(ciclopirox)
0.77%

FOR DERMATOLOGIC USE ONLY.
NOT FOR USE IN EYES.

Rx Only

DESCRIPTION

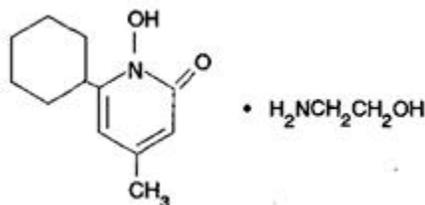
LOPROX[®] Lotion (ciclopirox) 0.77% is for topical use.

Each gram of LOPROX[®] Lotion contains 7.70 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 preservative.

LOPROX[®] 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:



LOPROX[®] 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 cm² 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 LOPROX[®] Lotion is equivalent to that of Loprox[®] Cream (ciclopirox olamine) 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

LOPROX[®] 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

LOPROX[®] Lotion is contraindicated in individuals who have shown hypersensitivity to any of its components.

WARNINGS

General

LOPROX[®] 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 LOPROX[®] 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 LOPROX[®] 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 LOPROX[®] Lotion 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 lotion and one patient using the lotion vehicle, and burning, which occurred in one patient using ciclopirox lotion.

DOSAGE AND ADMINISTRATION

Gently massage LOPROX[®] 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 LOPROX[®] Lotion the diagnosis should be redetermined. Patients with tinea versicolor usually exhibit clinical and mycological clearing after two weeks of treatment.

HOW SUPPLIED

Loprox[®] Lotion (ciclopirox) 0.77% is supplied in 30 ml bottles (NDC 99207-008-30), 60 ml bottles (NDC 99207-008-60).

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

Store between 5° - 25°C (41° - 77°F).

Covered by US Patent 3,883,545

Prescribing Information as of September 2001

Manufactured for:
MEDICIS, The Dermatology Company[®]
Scottsdale, AZ 85258
by: West Pharmaceutical Services Lakewood, Inc.
Lakewood, NJ 08701

REG TM THE AVENTIS GROUP

00830-08D



Each gram contains: 7.70 mg of Chlorhexine (as Chlorhexine Chloride) in a water-soluble form less quantity of Purified Water USP, Glycerin DEA, Octocrylene 1%, Mineral Oil USP, Stearyl Alcohol USP, Carbopol 980 NF, Polyethylene Glycol 400 NF, Hydroxyethyl Cellulose NF, Sodium Metabisulfite NF, Inert Acid USP, and Benzyl Alcohol NF (1%) as preservative.

Local Damage: Caution must be taken to avoid oral and mucous membrane irritation during the cleaning and rinsing. See package insert for full prescribing information.

Store at 2° - 8°C (36° - 77°F).

Manufactured for: MENCIS, The Dermatology Company, 7, Scottsdale, AZ 85258
by: West Pharmaceutical Services, Lakewood, Inc., Lakewood, CO 80401

REG. IN THE AVANTIS GROUP

Lot: 00830-10H
US Patent 3,883,545.

Exp:

NDC 59207-008-30

LOPROX LOTION
Chlorhexine 0.77% w/w

FOR DERMATOLOGIC USE ONLY
NOT FOR USE IN EYES.
Keep out of reach of children.
Bottle opens pushable to allow for vigorous shaking before each use.

30 ml
Rx Only

00830-100

BACK

FRONT

055642

055642



Rx Only
30 ml

Manufactured for:
MEDICIS, The Dermatology Company
Scottsdale, AZ 85258
by: West Pharmaceutical Services Labelwood, Inc.
Labelwood, NJ 08701
REG TM THE AVENTIS GROUP
US Patent 3,883,545.



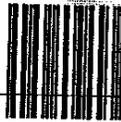
00830-060

LOPROX LOTION
(Eclaproxol 0.77% w/w)

NDC 99207-008-30

LOPROX LOTION
(Eclaproxol 0.77% w/w)

30ml



055642

FOR DERMATOLOGIC USE ONLY.
NOT FOR USE IN EYES.

Keep out of reach of children.
Bottle space provided to allow for
vigorous shaking before each use.
Usual Dosage: Gently massage into the
affected and surrounding skin areas twice
daily, in the morning and evening. See
package insert for full prescribing information.

Each gram contains: 770 mg of
Eclaproxol (as Eclaproxol Ointment) in a
water miscible lotion base consisting of
Purified Water USP, Glycerine, DL-
Cetyl Alcohol NF, Myristyl Alcohol NF,
Sorbitol Monolaurate NF, Stearyl Alcohol NF,
Polyorbene 60 NF, Myristyl Alcohol NF,
and Benzyl Alcohol NF (1%) in a preservative-
free at 5 °-25°C (41°-77°F).

Rx Only
30 ml



9 99207 00830 9

LOPROX LOTION
(Eclaproxol 0.77% w/w)

NDC 99207-008-30

055642



NDC 99207-008-60

LOPROX LOTION
[Ciclopirox] 0.77% (w/v)

FOR DERMATOLOGIC USE ONLY
NOT FOR USE IN EYES.
Keep out of reach of children.
Bottle opens provided to allow for
vigorous shaking before each use.

60 ml
Rx Only

0086010E

FRONT

BACK

Each gram contains: 7.70 mg of Ciclopirox
[as Ciclopirox Oxamine] in a water miscible
lotion base consisting of Purified Water USP,
Cocamide DEA, Octyldodecanol NF, Mineral
Oils USP, Stearyl Alcohol NF, Cetyl Alcohol NF,
Polyorbate 60 NF, Myristyl Alcohol NF,
Sorbitol Monolearate NF, Lactic Acid USP,
and Benzyl Alcohol NF (1%) as preservative.

Usual Dosage: Gently massage into the
affected and surrounding skin areas twice
daily, in the morning and evening. See
package insert for full prescribing information.

Store at 5°-25°C (41°-77°F).

Manufactured for:
MEDCIS, The Dermatology Company®
Scottsdale, AZ 85258

by: West Pharmaceutical Services Lakewood,
Inc., Lakewood, NJ 08701

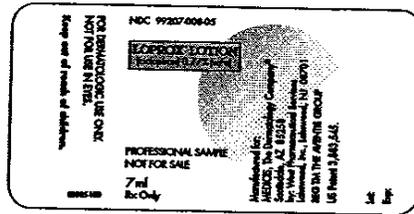
REG TM THE AVENTIS GROUP

Lot:

00860-10F

Exp:

US Patent
3,883,545.



055644
055644

LOPROX LOTION
[ciclopirox] 0.77% (w/w)

NDC 99207-00805

12 x 7 ml
Rx Only



99207-00805

LOPROX LOTION
[ciclopirox] 0.77% (w/w)

NDC 99207-00805

12 x 7 ml
Rx Only

LOPROX LOTION
[ciclopirox] 0.77% (w/w)

NDC 99207-00805

12 x 7 ml
Rx Only

Each gram contains 7.70 mg of ciclopirox base consisting of purified Water USP, Cocamide DEA, Octyldodecanol NE, Mineral Oil USP, Stearyl Alcohol NF, Cetyl Alcohol NF, Polyethylene 40 NF, Myristyl Alcohol NF, Benzyl Alcohol NF, Benzyl Salicylate NF, and Benzyl Alcohol NF (1%) as a preservative. Store at 5° - 25°C (41° - 77°F).

Not intended for use in the eye.

Medicated for Ophthalmology, Category 1
 By: Vial Pharmaceutical Services, Littlewood, Inc., Littlewood, NJ 08201

MEDICS
The Ophthalmic Company

02805040

FOR Ophthalmologic USE ONLY
NOT FOR USE IN EYES.
 Keep out of reach of children.
 Single doses provided to allow for vigorous shaking before each use.

Usual Dosage: Gently massage into the affected and surrounding skin three times daily in the morning and evening. See package insert for full prescribing information.

US Patent 3,883,545.

PROFESSIONAL SAMPLE - NOT FOR SALE

30 ml and 60 ml bottles available

12 x 7 ml
Rx Only

