

NDA 18-748/S-011  
Page 3

APPROVED

AUG 17 2001

Directions for puncturing tube seal:  
Remove cap. Turn cap upside down and place puncture tip onto tube. Push cap until tube end is punctured.  
Screw cap back on to reseat tube.  
Use the cap to seal the tube only.  
See insert for additional instructions.  
② Each gram contains 7.70 mg of Cyclopirox (as Cyclopirox Chloride) in a pH-balanced, antibiotic cream base consisting of Purified Water USP, Octyldodecanol NF, Stearyl Alcohol NF, Stearyl Alcohol NF, Polyethylene Glycol 400, and Benzyl Alcohol USP. It also contains preservatives Sorbitan Monostearate NF, Lactic Acid USP, and Benzyl Alcohol USP.  
Store at controlled room temperature 15°-30°C (59°-86°F).  
Keep out of reach of children.

NDC 99207-009-15 ③

15 grams

**Loprox<sup>®</sup> Cream**  
(ciclopirox) 0.77%

FOR DERMATOLOGIC USE ONLY. NOT FOR USE IN EYES.  
Rx Only

④

Manufactured for:  
MEDICIS, The Dermatology Company  
Pharmaceutical Division  
P.O. Box 2785018  
Frankfurt am Main  
D-65928 Frankfurt am Main  
Made in Germany

REG. TM HOECHST AG

NDC 99207-009-15 ⑤

15 grams

**Loprox<sup>®</sup> Cream**  
(ciclopirox) 0.77%

FOR DERMATOLOGIC USE ONLY. NOT FOR USE IN EYES.  
Rx Only

- ① Change To:  
Mineral Oil Light, NF.
- ② Delete.
- ③ Revise NDC.
- ④ Revise firm name, address as needed.

XXXXXXXXXX  
XXXXXXXXXX



131361 C

3 9920-7009-15 3



NDC 99207-009-15 ③  
15 grams  
Loprox<sup>®</sup>  
(ciclopirox) 0.77%  
Cream

LOT: EXP:



---

**This is a representation of an electronic record that was signed electronically and  
this page is the manifestation of the electronic signature.**

---

/s/

---

Wilson H. DeCamp  
8/17/01 04:24:27 PM  
approved