

Loprox® (ciclopirox) Cream, 0.77% (NDA 18748)
Final Printed Carton and Container Labels for Approved NDA 18748
Trade 90 gram Tube: IT053-R1

Confidential

NDC 43538-540-90 **For Topical Use Only**
Not for use in eyes **90g**
Rx Only



LOPROX® (ciclopirox)
Cream, 0.77%

 **MEDIMETRIKS**
PHARMACEUTICALS, INC.

Keep out of reach of children.
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: 7.70 mg of ciclopirox (as ciclopirox olamine) 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, Sorbitan Monostearate NF, Lactic Acid USP, and Benzyl Alcohol NF (1%) as preservative.
Store at 15° - 30°C (59° - 86°F).
See Crimp for Lot No. and Expiration Date.
Manufactured for: Medimetrics Pharmaceuticals, Inc., 383 Route 46 West, Fairfield, NJ 07004-2402 USA
Manufactured by: Teligent Pharma, Inc., Buena, NJ 08310



IT053-R1

Loprox® (ciclopirox) Cream, 0.77% (NDA 18748)
Final Printed Carton and Container Labels for Approved NDA 18748
Trade 90 gram Carton: IC180-RI

Confidential

Each gram contains: 7.70 mg of ciclopirox (as ciclopirox olamine) 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, Sorbitan Monostearate NF, Lactic Acid USP, and Benzyl Alcohol NF (1%) as preservative.
Store at 15° - 30°C (59° - 86°F).
Manufactured for: Medimetrix Pharmaceuticals, Inc.
383 Route 46 West, Fairfield, NJ 07004-2402 USA
Manufactured by: Teigen Pharma, Inc., Buena, NJ 08310
IC180-RI 3 N
43538 54090 8



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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 on to reseal tube.



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