INDICATIONS AND USAGE
LOPROX Shampoo is indicated for the topical treatment of seborrheic dermatitis of the scalp in adults.

DOSE AND ADMINISTRATION
Apply approximately 1 teaspoon of LOPROX Shampoo to the scalp twice per week for 4 weeks. For topical use only. Not for oral, oral, or intravaginal use.

DIAGNOSIS AND STRENGTHS
Each gram (equivalent to 0.96 mL) of LOPROX Shampoo contains 10 mg ciclopirox in a colorless and translucent shampoo base.

DOSE FORMS AND STRENGTHS
Shampoo, 1% (3)

CONTRAINDICATIONS
None (4)

WARNINGS AND PRECAUTIONS
Avoid contact with eyes. (5.1)

ADVERSE REACTIONS
The most frequently reported adverse reactions are pruritus, burning, and erythema. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Valeant Pharmaceuticals North America LLC at 1-800-321-4576 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

FULL PRESCRIBING INFORMATION: CONTENTS*
1 INDICATIONS AND USAGE
2 DOSAGE AND ADMINISTRATION
3 DOSAGE FORMS AND STRENGTHS
4 CONTRAINDICATIONS
5 WARNINGS AND PRECAUTIONS
6 ADVERSE REACTIONS
7 USE IN SPECIFIC POPULATIONS
8.1 Pregnancy
8.3 Nursing Mothers
9 ADVERSE REACTIONS
10 CLINICAL PHARMACOLOGY
11 DESCRIPTION
12 CLINICAL PHARMACOLOGY
12.1 Mechanism of Action
12.2 Pharmacodynamics
12.3 Pharmacokinetics
12.4 Microbiology
13 NONCLINICAL TOXICITY
14 CLINICAL STUDIES
15 HOW SUPPLIED/STORAGE AND HANDLING
16 PATIENT COUNSELING INFORMATION
17 PATIENT INFORMATION
18 DOSAGE FORMS AND STRENGTHS
19 CONTRAINDICATIONS
20 WARNINGS AND PRECAUTIONS
21 ADVERSE REACTIONS
22 USE IN SPECIFIC POPULATIONS
23 CLINICAL PHARMACOLOGY
24 DESCRIPTION
25 NONCLINICAL TOXICITY
26 CLINICAL STUDIES
27 HOW SUPPLIED/STORAGE AND HANDLING
28 PATIENT COUNSELING INFORMATION
29 PATIENT INFORMATION
30 DOSAGE FORMS AND STRENGTHS
31 CONTRAINDICATIONS
32 WARNINGS AND PRECAUTIONS
33 ADVERSE REACTIONS
34 USE IN SPECIFIC POPULATIONS
35 CLINICAL PHARMACOLOGY
36 DESCRIPTION
37 NONCLINICAL TOXICITY
38 CLINICAL STUDIES
39 HOW SUPPLIED/STORAGE AND HANDLING
40 PATIENT COUNSELING INFORMATION
41 PATIENT INFORMATION
42 DOSAGE FORMS AND STRENGTHS
43 CONTRAINDICATIONS
44 WARNINGS AND PRECAUTIONS
45 ADVERSE REACTIONS
46 USE IN SPECIFIC POPULATIONS
47 CLINICAL PHARMACOLOGY
48 DESCRIPTION
49 NONCLINICAL TOXICITY
50 CLINICAL STUDIES
51 HOW SUPPLIED/STORAGE AND HANDLING
52 PATIENT COUNSELING INFORMATION
53 PATIENT INFORMATION
54 DOSAGE FORMS AND STRENGTHS
55 CONTRAINDICATIONS
56 WARNINGS AND PRECAUTIONS
57 ADVERSE REACTIONS
58 USE IN SPECIFIC POPULATIONS
59 CLINICAL PHARMACOLOGY
60 DESCRIPTION
61 NONCLINICAL TOXICITY
62 CLINICAL STUDIES
63 HOW SUPPLIED/STORAGE AND HANDLING
64 PATIENT COUNSELING INFORMATION
65 PATIENT INFORMATION
66 DOSAGE FORMS AND STRENGTHS
67 CONTRAINDICATIONS
68 WARNINGS AND PRECAUTIONS
69 ADVERSE REACTIONS
70 USE IN SPECIFIC POPULATIONS
71 CLINICAL PHARMACOLOGY
72 DESCRIPTION
73 NONCLINICAL TOXICITY
74 CLINICAL STUDIES
75 HOW SUPPLIED/STORAGE AND HANDLING
76 PATIENT COUNSELING INFORMATION
77 PATIENT INFORMATION
78 DOSAGE FORMS AND STRENGTHS
79 CONTRAINDICATIONS
80 WARNINGS AND PRECAUTIONS
81 ADVERSE REACTIONS
82 USE IN SPECIFIC POPULATIONS
83 CLINICAL PHARMACOLOGY
84 DESCRIPTION
85 NONCLINICAL TOXICITY
86 CLINICAL STUDIES
87 HOW SUPPLIED/STORAGE AND HANDLING
88 PATIENT COUNSELING INFORMATION
89 PATIENT INFORMATION
90 DOSAGE FORMS AND STRENGTHS
91 CONTRAINDICATIONS
92 WARNINGS AND PRECAUTIONS
93 ADVERSE REACTIONS
94 USE IN SPECIFIC POPULATIONS
95 CLINICAL PHARMACOLOGY
96 DESCRIPTION
97 NONCLINICAL TOXICITY
98 CLINICAL STUDIES
99 HOW SUPPLIED/STORAGE AND HANDLING
100 PATIENT COUNSELING INFORMATION
101 PATIENT INFORMATION
102 DOSAGE FORMS AND STRENGTHS
103 CONTRAINDICATIONS
104 WARNINGS AND PRECAUTIONS
105 ADVERSE REACTIONS
106 USE IN SPECIFIC POPULATIONS
107 CLINICAL PHARMACOLOGY
108 DESCRIPTION
109 NONCLINICAL TOXICITY
110 CLINICAL STUDIES
111 HOW SUPPLIED/STORAGE AND HANDLING
112 PATIENT COUNSELING INFORMATION
113 PATIENT INFORMATION
114 DOSAGE FORMS AND STRENGTHS
115 CONTRAINDICATIONS
116 WARNINGS AND PRECAUTIONS
117 ADVERSE REACTIONS
118 USE IN SPECIFIC POPULATIONS
119 CLINICAL PHARMACOLOGY
120 DESCRIPTION
121 NONCLINICAL TOXICITY
122 CLINICAL STUDIES
123 HOW SUPPLIED/STORAGE AND HANDLING
124 PATIENT COUNSELING INFORMATION
125 PATIENT INFORMATION
126 DOSAGE FORMS AND STRENGTHS
127 CONTRAINDICATIONS
128 WARNINGS AND PRECAUTIONS
129 ADVERSE REACTIONS
130 USE IN SPECIFIC POPULATIONS
131 CLINICAL PHARMACOLOGY
132 DESCRIPTION
133 NONCLINICAL TOXICITY
134 CLINICAL STUDIES
135 HOW SUPPLIED/STORAGE AND HANDLING
136 PATIENT COUNSELING INFORMATION
137 PATIENT INFORMATION
138 DOSAGE FORMS AND STRENGTHS
139 CONTRAINDICATIONS
140 WARNINGS AND PRECAUTIONS
141 ADVERSE REACTIONS
142 USE IN SPECIFIC POPULATIONS
143 CLINICAL PHARMACOLOGY
144 DESCRIPTION
145 NONCLINICAL TOXICITY
146 CLINICAL STUDIES
147 HOW SUPPLIED/STORAGE AND HANDLING
148 PATIENT COUNSELING INFORMATION
149 PATIENT INFORMATION
150 DOSAGE FORMS AND STRENGTHS
151 CONTRAINDICATIONS
152 WARNINGS AND PRECAUTIONS
153 ADVERSE REACTIONS
154 USE IN SPECIFIC POPULATIONS
155 CLINICAL PHARMACOLOGY
156 DESCRIPTION
157 NONCLINICAL TOXICITY
158 CLINICAL STUDIES
159 HOW SUPPLIED/STORAGE AND HANDLING
160 PATIENT COUNSELING INFORMATION
161 PATIENT INFORMATION
162 DOSAGE FORMS AND STRENGTHS
163 CONTRAINDICATIONS
164 WARNINGS AND PRECAUTIONS
165 ADVERSE REACTIONS
166 USE IN SPECIFIC POPULATIONS
167 CLINICAL PHARMACOLOGY
168 DESCRIPTION
169 NONCLINICAL TOXICITY
170 CLINICAL STUDIES
171 HOW SUPPLIED/STORAGE AND HANDLING
172 PATIENT COUNSELING INFORMATION
173 PATIENT INFORMATION
174 DOSAGE FORMS AND STRENGTHS
175 CONTRAINDICATIONS
176 WARNINGS AND PRECAUTIONS
177 ADVERSE REACTIONS
178 USE IN SPECIFIC POPULATIONS
179 CLINICAL PHARMACOLOGY
180 DESCRIPTION
181 NONCLINICAL TOXICITY
182 CLINICAL STUDIES
183 HOW SUPPLIED/STORAGE AND HANDLING
184 PATIENT COUNSELING INFORMATION
185 PATIENT INFORMATION
186 DOSAGE FORMS AND STRENGTHS
187 CONTRAINDICATIONS
188 WARNINGS AND PRECAUTIONS
189 ADVERSE REACTIONS
190 USE IN SPECIFIC POPULATIONS
191 CLINICAL PHARMACOLOGY
192 DESCRIPTION
193 NONCLINICAL TOXICITY
194 CLINICAL STUDIES
195 HOW SUPPLIED/STORAGE AND HANDLING
196 PATIENT COUNSELING INFORMATION
197 PATIENT INFORMATION
198 DOSAGE FORMS AND STRENGTHS
199 CONTRAINDICATIONS
200 WARNINGS AND PRECAUTIONS
201 ADVERSE REACTIONS
202 USE IN SPECIFIC POPULATIONS
203 CLINICAL PHARMACOLOGY
204 DESCRIPTION
205 NONCLINICAL TOXICITY
206 CLINICAL STUDIES
207 HOW SUPPLIED/STORAGE AND HANDLING
208 PATIENT COUNSELING INFORMATION
209 PATIENT INFORMATION
210 Table 1. Effective Treatment Rates at Weeks 4 in Trials 1 and 2

- Study 1 232/349 (68%) 60/192 (31%)
- Study 2 65/250 (26%) 32/439 (15%)
- Efficacy for American African subjects was not demonstrated, although only 53 African American subjects were enrolled in the pivotal trials.
- The following in vitro genotoxicity tests have been conducted: a) ciclopirox: evaluation of the Ames Salmonella and E. coli assay (negative); b) chromosome aberration assays in V79 Chinese hamster lung fibroblast cells, with and without metabolic activation (positive); c) chromosome aberration assays in V79 Chinese hamster lung fibroblast cells in the presence of Supplemental Fe+, and with and without metabolic activation (negative); gene mutation test using the S. typhimurium strains TA97, TA98, TA100, TA102, TA104, and TA1535, and Chinese hamster lung fibroblast cells (negative); and a primary DNA damage assay (i.e., unscheduled DNA synthesis in Chinese hamster V79 cells following exposure to 5-ethyl-2′-deoxyuridine) in vitro cell transformation assay in BALB/c 3T3 cells was not possible for cell transformation detection. A positive test was achieved in Chinese hamster bone marrow cytogenetic assay, ciclopirox was negative for chromosome aberrations at a dosage of 5,000 mg/kg body weight.
- A combined oral fetal and embryofetal developmental study was conducted in rats with ciclopirox olamine. No effect on fertility or reproductive performance was noted at the highest dose tested of 3.85 mg/kg/day ciclopirox (approximately 1.3 times the maximum recommended human dose based on body surface area).
The patient should be instructed:

- Use LOPROX Shampoo as directed by the physician. Avoid contact with the eyes. If contact occurs, rinse thoroughly with water. LOPROX Shampoo is for external use on the scalp only. Do not swallow.
- Use LOPROX Shampoo for seborrheic dermatitis for the full treatment time even though symptoms may have improved. Notify the physician if there is no improvement after 4 weeks.
- Inform the physician if the area of application shows signs of increased irritation (redness, itching, burning, blistering, swelling, or oozing).

Manufactured for: Valeant Pharmaceuticals North America LLC

By: Valeant Pharmaceuticals International, Inc.

U.S. Patent Numbers 7,981,909 and 8,227,490

Loprox is a trademark of Valeant Pharmaceuticals International, Inc. or its affiliates.

©Valeant Pharmaceuticals North America LLC

9505301 20001320B

Important: For use on the scalp only. Do not get LOPROX Shampoo in your eyes, mouth, or vagina.

What is LOPROX Shampoo?
LOPROX Shampoo is a prescription medicine used on the scalp to treat adults with a skin condition called seborrheic dermatitis. It is not known if LOPROX Shampoo is safe and effective in children under 16 years of age.

What should I tell my doctor before using LOPROX Shampoo?

Before using LOPROX Shampoo, tell your doctor if you:

- Have any other medical conditions
- Are pregnant or plan to become pregnant. It is not known if LOPROX Shampoo will harm your unborn baby.
- Are breastfeeding or plan to breastfeed. It is not known if LOPROX Shampoo passes into your breast milk.
- Are taking prescription and nonprescription medicines, vitamins, and herbal supplements.
- Know the medicines you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine.

How should I use LOPROX Shampoo?

- Use LOPROX Shampoo exactly as your doctor tells you to use it.
- Wash your hair using LOPROX Shampoo 2 times each week for 4 weeks. There should be at least 3 days between each time you use LOPROX Shampoo.
- Use LOPROX Shampoo for 4 weeks even if your skin condition improves.
- Tell your doctor if your scalp condition is not getting better after you have used LOPROX Shampoo for 4 weeks.
- Do not swallow LOPROX Shampoo.
- Avoid getting LOPROX Shampoo in your eyes. If LOPROX Shampoo gets into your eyes, rinse them well with water.

How should I store LOPROX Shampoo?

- Wet your hair and apply approximately 1 teaspoon of LOPROX Shampoo to your scalp. You may use up to 2 teaspoons of LOPROX Shampoo if you have long hair. Lather and leave LOPROX Shampoo on your hair and scalp for 3 minutes. You may use a timer.
- After 3 minutes have passed, rinse your hair and scalp.

What are the possible side effects of LOPROX Shampoo?

The most common side effects of LOPROX Shampoo include:

- Itching, burning, and redness of the scalp. Tell your doctor if you get any of these symptoms and they become worse or do not go away, or if you get blistering, swelling, or oozing in your scalp.
- Itching, burning, and redness in your eyes, mouth, or vagina.

These are not all the possible side effects of LOPROX Shampoo. For more information, ask your doctor.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store LOPROX Shampoo?

- Store LOPROX Shampoo at room temperature, between 59° to 86°F (15° to 30°C).
- Safely throw away any unused LOPROX Shampoo after you finish your treatment.

Keep LOPROX Shampoo and all medicines out of reach of children.

General information about LOPROX Shampoo

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use LOPROX Shampoo for a condition for which it was not prescribed. Do not give LOPROX Shampoo to other people, even if they have the same symptoms you have. It may harm them.

You can ask your pharmacist or doctor for information about LOPROX Shampoo that is written for health professionals.

For more information about LOPROX Shampoo, call 1-800-321-4576.

What are the ingredients in LOPROX Shampoo?

Active ingredient: ciclopirox

Inactive ingredients: disodium laureth sulfosuccinate, laueth-2, purified water, sodium chloride, and sodium laureth sulfate.

This Patient Information has been approved by the U.S. Food and Drug Administration.

Manufactured for:

Valeant Pharmaceuticals North America LLC

Bridgewater, NJ 08807 USA

By: Valeant Pharmaceuticals International, Inc.

Laval, Quebec H7L 4A8, Canada

U.S. Patent Numbers 7,981,909 and 8,227,490

Loprox is a trademark of Valeant Pharmaceuticals International, Inc. or its affiliates.

©Valeant Pharmaceuticals North America LLC

9505301 20001320B

Rev. 06/2017

9505301 20001320B

©Valeant Pharmaceuticals North America LLC

International, Inc. or its affiliates.

Loprox is a trademark of Valeant Pharmaceuticals

U.S. Patent Numbers 7,981,909 and 8,227,490

Laval, Quebec H7L 4A8, Canada

Valeant Pharmaceuticals International, Inc.

By:

Bridgewater, NJ 08807 USA

Manufactured for:

U.S. Food and Drug Administration.

This Patient Information has been approved by the

Manufactured for:

Valeant Pharmaceuticals North America LLC

Bridgewater, NJ 08807 USA

By: Valeant Pharmaceuticals International, Inc.

Laval, Quebec H7L 4A8, Canada

U.S. Patent Numbers 7,981,909 and 8,227,490

Loprox is a trademark of Valeant Pharmaceuticals

International, Inc. or its affiliates.

©Valeant Pharmaceuticals North America LLC

9505301 20001320B

Rev. 06/2017

IMPORTANT: For use on the scalp only. Do not get LOPROX Shampoo in your eyes, mouth, or vagina.

What is LOPROX Shampoo?
LOPROX Shampoo is a prescription medicine used on the scalp to treat adults with a skin condition called seborrheic dermatitis.

It is not known if LOPROX Shampoo is safe and effective in children under 16 years of age.

What should I tell my doctor before using LOPROX Shampoo?

Before using LOPROX Shampoo, tell your doctor if you:

- Have any other medical conditions
- Are pregnant or plan to become pregnant. It is not known if LOPROX Shampoo will harm your unborn baby.
- Are breastfeeding or plan to breastfeed. It is not known if LOPROX Shampoo passes into your breast milk.
- Are taking prescription and nonprescription medicines, vitamins, and herbal supplements.
- Know the medicines you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine.

How should I use LOPROX Shampoo?

- Use LOPROX Shampoo exactly as your doctor tells you to use it.
- Wash your hair using LOPROX Shampoo 2 times each week for 4 weeks. There should be at least 3 days between each time you use LOPROX Shampoo.
- Use LOPROX Shampoo for 4 weeks even if your skin condition improves.
- Tell your doctor if your scalp condition is not getting better after you have used LOPROX Shampoo for 4 weeks.
- Do not swallow LOPROX Shampoo.
- Avoid getting LOPROX Shampoo in your eyes. If LOPROX Shampoo gets into your eyes, rinse them well with water.

How should I store LOPROX Shampoo?

- Wet your hair and apply approximately 1 teaspoon of LOPROX Shampoo to your scalp. You may use up to 2 teaspoons of LOPROX Shampoo if you have long hair. Lather and leave LOPROX Shampoo on your hair and scalp for 3 minutes. You may use a timer.
- After 3 minutes have passed, rinse your hair and scalp.

What are the possible side effects of LOPROX Shampoo?

The most common side effects of LOPROX Shampoo include:

- Itching, burning, and redness of the scalp. Tell your doctor if you get any of these symptoms and they become worse or do not go away, or if you get blistering, swelling, or oozing in your scalp.
- Itching, burning, and redness in your eyes, mouth, or vagina.

These are not all the possible side effects of LOPROX Shampoo. For more information, ask your doctor.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.