Mechanism of Action
Ciclopirox has been shown to be active against a wide range of dermatophytes in vitro and in vivo. The mechanism of action of ciclopirox has been investigated using various in vitro and in vivo infection models. One in vitro study demonstrated that ciclopirox inhibited the growth of dermatophytic onychomycoses, after application of Ciclopirox Topical Solution, 8%, (Nail Lacquer). The inhibit of this compound.

INDICATIONS AND USAGE
Ciclopirox Topical Solution, 8%, (Nail Lacquer) is indicated for the treatment of onychomycosis caused by Trichophyton rubrum, Trichophyton mentagrophytes, and Epidermophyton floccosum. The penetra...
The effectiveness and safety of Ciclopirox Topical Solution, 8% (Nail Lacquer), were obtained from two double-blind, placebo-controlled studies conducted in the US. In these studies, patients with onychomycosis of the toenail without lunula involvement were treated with ciclopirox topical solution 8% in comparison with vehicle controls. The results of use of ciclopirox Topical Solution, 8%, (Nail Lacquer), in studies for the endpoint "complete cure" (clear nail and negative mycology) are presented below. The patient should be told:

- Ciclopirox Topical Solution, 8% (Nail Lacquer), should be used only under medical supervision as described above.
- The effectiveness and safety of Ciclopirox Topical Solution, 8% (Nail Lacquer), were obtained from two double-blind, placebo-controlled studies conducted in the US. In these studies, patients with onychomycosis were treated with ciclopirox topical solution 8% in comparison with vehicle controls. The results of use of ciclopirox Topical Solution, 8%, (Nail Lacquer), in studies for the endpoint "complete cure" (clear nail and negative mycology) are presented below.

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Patients</th>
<th>Cured</th>
<th>Almost Cured</th>
<th>Null</th>
<th>Not Assessed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ciclopirox</td>
<td>122</td>
<td>112</td>
<td>314</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Placebo</td>
<td>119</td>
<td>111</td>
<td>308</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

The summary of reported patient outcomes for the ITT population at 12 weeks following the start of treatment are presented below. The patient should be told:

- Use Ciclopirox Topical Solution, 8% (Nail Lacquer), as directed by health-care professional. Avoid contact with the eye and excess surroundings. Contact with drop does not rinse immediately following the treated site should be avoided. Ciclopirox Topical Solution, 8% (Nail Lacquer), is for external use only.
- Ciclopirox Topical Solution, 8% (Nail Lacquer), should be applied even over the lesions. The treated site and 3 cm surrounding normal skin should be cleansed with a nonalcoholic, alcohol-free preparation; such as ciclopirox Topical Solution, 8% (Nail Lacquer) should be applied to the treated hand and foot, regardless of the site (e.g., contact). Contact with the surrounding skin may produce mild, transient irritation. (continued)

- Avoid use near heat or open flame, because product is flammable. Use only under medical supervision as described above.
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- Cure*
- Clear nail and negative mycology
- 10% nail involvement and negative mycology
- Negative mycology**
- Achieved complete cure at week 48
- The incidence of nail disorders was similar between the treat groups (i.e., ciclopirox Topical Solution, 8%, (Nail Lacquer), and placebo). In clinical studies, greater than or equal to 12% of patients were at risk for some of these adverse events during the study.
- In patients treated with ciclopirox Topical Solution, 8% (Nail Lacquer), or the vehicle base, the following occurs:
- Cures
- Clear nail and negative mycology
- 10% nail involvement and negative mycology
- Negative mycology**

- After the patient has reported signs of increased irritation (redness, itching, burning, stinging, swelling) or severe irritation (redness), ciclopirox topical solution 8% (Nail Lacquer) should be stopped immediately and professional care should be sought.
- Without medical supervision, inadvertent ophthalmic contact with the eyes or skin, or failure to account for the film-forming nature of the resin, may have been confounded because of the film-forming nature of the resin.
- Percentage of patients with positive response on the lacquer formulation in the in vitro transformation assay (negative). In an in vivo study, 80% of patients treated with ciclopirox Topical Solution, 8%, (Nail Lacquer), or the vehicle base, the following occurs:
- Cure*
- Clear nail and negative mycology
- 10% nail involvement and negative mycology
- Negative mycology**

Contraindications:

- Avoid use near heat or open flame, because product is flammable.

Warnings:

- Use Ciclopirox Topical Solution, 8%, (Nail Lacquer), as directed by your health-care professional.

- Do not use ciclopirox Topical Solution, 8%, (Nail Lacquer), on the nail plate, subungual area, or surrounding skin. For use on nails and immediately adjacent skin only.
- In patients treated with ciclopirox Topical Solution, 8% (Nail Lacquer), or the vehicle base, the following occurs:
- Cure*
- Clear nail and negative mycology
- 10% nail involvement and negative mycology
- Negative mycology**

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