The mechanism of action of ciclopirox has been investigated using various in vivo and in vitro models. The degradation of peroxides within the fungal cell. The clinical significance of this observation is unknown. Nutrients have been utilized to determine ciclopirox minimum inhibitory concentration (MIC) for several T. rubrum strains. In two vehicle-controlled trials, patients applied ciclopirox topical solution, 8% to all toenails and adjacent skin. From baseline to endpoint, there was a decrease in number of clinical cure (clear nail and negative mycology) and in two studies for the endpoint “almost clear” ≤10% residual nail involvement. Six months of therapy with professional treatment was considered the full treatment time to achieve a clear or almost clear nail (defined as 10% or less residual nail involvement). Patients who achieved a complete cure were considered the ITT population at 12 weeks following the end of treatment. The results of use of ciclopirox topical solution, 8% in treatment of onychomycosis of the toenail are presented below. Note that post-treatment efficacy assessments were scheduled at 48 weeks for the onychomycosis population. The summary of reported patient outcomes for the ITT population at 12 weeks following the end of treatment are presented below. Of the 112 patients treated with ciclopirox topical solution, 8% two patients had missing efficacy data. The efficacy of ciclopirox topical solution, 8% was confirmed by in vitro ex vivo human nail preparation.

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Patient Instructions

1. Before starting treatment, remove any loose nail or nail material using nail clippers or nail files. If you have difficulty removing the cornifications or hard skin, ask your health care professional for advice on the best method to use.

2. If there is no clinical evidence with patients with insulin dependent diabetes or who have diabetes and are on oral hypoglycemic agents, the patient's health care professional should be informed. If the patient has a history of insulin dependent diabetes mellitus or diabetes mellitus, the patient's health care professional should be informed.

3. Patients should have detailed instructions reporting the use of ciclopirox topical solution, so that the patient can understand the management program for medications to achieve maximal benefit with the use of this product.

4. Use ciclopirox topical solution, 8% to treat the following nails:
   - Toenails (all digits)
   - Finger nails (except thumb)

5. Up to 48 weeks of daily applications with ciclopirox topical solution, 8% and professional management program for onychomycosis. Removal of the unattached, infected nail, as frequently as monthly, trimming of onycholytic nail, and debridement of the nailplate may be necessary to optimize the topical treatment of toenails.

6. Protect from light (e.g., store the bottle in the carton after every use).

7. Store at controlled room temperature. [See USP, “Controlled Room Temperature.”]