Extina® (ketoconazole) Foam, 2% is indicated for the treatment of fungal infections.

INDICATIONS AND USAGE
Rx only

Extina® (ketoconazole) Foam, 2% is indicated for the topical treatment of seborrheic dermatitis in immunocompromised patients 12 years of age and older. Safety and efficacy of Extina Foam for treatment of fungal infections have not been established.

CONTRAINDICATIONS
None

WARRANTINGS AND PRECAUTIONS
Contact Sensitization
Extina Foam may result in contact sensitization, including photoallergenicity. [See Adverse Reactions, Dermal Safety Studies]

Flammable Contents
The contents of Extina Foam include alcohol and propylene/ozonate, which are flammable. Avoid fire, flame and/or smoking during and immediately following application. Do not puncture and/or incinerate the containers. Do not expose containers to heat and/or store at temperatures above 120°F (49°C).

Systemic Effects
Hepatitis has been seen with orally administered ketoconazole (1:10,000 reported incidence). Lowered testosterone and ACTH-induced corticosteroid serum levels have been seen with high doses of orally administered ketoconazole. These effects have not been seen with topical ketoconazole.

ADVERSE REACTIONS
Adverse Reactions in Clinical Trials
Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug, and may not reflect the rates observed in practice. The adverse reaction information from clinical trials does, however, provide a basis for identifying the adverse reactions that appear to be related to drug use and for approximating rates. The safety data presented in Table 1 (below) reflect exposure to Extina Foam in 672 subjects, 12 years and older with seborrheic dermatitis. Subjects applied Extina Foam or vehicle foam twice daily for 4 weeks to affected areas on the face, scalp, and/or chest. Adverse reactions occurring in >1% of subjects are presented in Table 1.

Table 1: Adverse Reactions Reported by >1% Subjects in Clinical Trials

<table>
<thead>
<tr>
<th>Adverse Reactions</th>
<th>Extina Foam</th>
<th>Vehicle Foam</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application site reaction</td>
<td>143 (6%)</td>
<td>69 (5%)</td>
</tr>
<tr>
<td>Application site burning</td>
<td>33 (2%)</td>
<td>21 (2%)</td>
</tr>
<tr>
<td>Application site reaction</td>
<td>24 (5%)</td>
<td>17 (2%)</td>
</tr>
<tr>
<td>Application site reaction</td>
<td>28 (4%)</td>
<td>13 (2%)</td>
</tr>
</tbody>
</table>

Table 1: Adverse Reactions Reported by >1% Subjects in Clinical Trials

ADVERSE REACTIONS
Application site reactions that were reported in >1% of subjects were dryness, erythema, irritation, paresthesia, pruritus, rash and warmth.

Dermal Safety Studies
In a photoproliferation study, 9 of 33 subjects (27%) had reactions during the challenge period at both the irritated and non-irritated sites treated with Extina Foam. Extina Foam may cause contact sensitization.

USE IN SPECIFIC POPULATIONS
Pregnancy
Teratogenic Effects, Pregnancy Category C:
Ketoconazole has been shown to be teratogenic (syndactyly and oligodactyly) in the rat when given orally in the dose range of 48 mg/kg/day. It is not known whether Extina Foam in human milk, caution should be exercised when Extina Foam is administered to women who are breastfeeding.

Pediatric Use
The safety and effectiveness of Extina Foam in pediatric patients less than 12 years of age have not been established.

CONTRAINDICATIONS
None

APPLICATIONS OF FERTILITY
Teratogenic Effects, Pregnancy Category C:
Pregnancy
Long-term animal studies have not been performed to evaluate the carcinogenicity of Extina Foam in mice. In oral carcinogenicity studies in mice (18-months) and rats (24-months) at dose levels of 5, 20 and 80 mg/kg/day ketoconazole was not carcinogenic. The high dose in these studies was approximately 2.4 to 4.8 times the expected topical dose in humans based on a mg/m2 comparison. In a 2-year carcinogenicity study in mice, ketoconazole did not express any mutagenic potential. In three in vivo assays (sister chromatid exchange in humans, dominant lethal and micronucleus tests in mice), ketoconazole did not exhibit any genotoxic potential.

At oral dose levels of 75 mg/kg/day and rats (24-months) at dose levels of 5, 20 and 80 mg/kg/day ketoconazole was not carcinogenic. The high dose in these studies was approximately 2.4 to 4.8 times the expected topical dose in humans based on a mg/m2 comparison. In a bacterial reverse mutation assay, ketoconazole did not express any mutagenic potential. In three in vivo assays (sister chromatid exchange in humans, dominant lethal and micronucleus tests in mice), ketoconazole did not exhibit any genotoxic potential.

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Adverse events included only slight dryness post treatment, which was managed with application of a daily moisturizer, he said.

The findings are comparable with those from other studies of this device as reported in the literature, all of which have demonstrated its efficacy for the treatment of acne, said Dr. Gold of the Tennessee Clinical Research Center in Nashville.

Device Uses Light, Vacuum To Improve Acne Lesions

KISSIMMEE, Fla. — Photopneumatic therapy is highly effective and nearly painless for the treatment of acne vulgaris, according to Dr. Michael Gold.

The recently approved Aethera PPx laser system—which combines light energy and a vacuum apparatus to cleanse pores and destroy bacteria associated with acne vulgaris—was used to treat both purutidal and comedonal acne in an open-label study involving 11 patients with mild to moderate acne, Dr. Gold said at the annual meeting of the American Society for Laser Medicine and Surgery.

Up to four treatments were provided at 3-week intervals, and all of the patients experienced significant and rapid clearing of their lesions, he reported.

Reported pain was minimal in more than 85% of patients, and 82% of patients said they were moderately or very satisfied with the outcomes.

Drying and flattening of the lesions were noted within 2 days of treatment in more than half of the patients, and most experienced sustained clearance at 3-month follow-up with a 78% reduction in inflammatory lesions, and up to a 70% reduction in noninflammatory lesions, Dr. Gold said.

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The findings are comparable with those from other studies of this device as reported in the literature, all of which have demonstrated its efficacy for the treatment of acne, said Dr. Gold of the Tennessee Clinical Research Center in Nashville.

Given that more than one-third of dermatology visits are associated with acne, this device—which is the only device that has been approved by the Food and Drug Administration to treat both comedonal and inflammatory acne, and which appears to be effective even in those patients who are nonresponders to traditional therapies—is a welcome addition to the acne treatment armamentarium, he concluded.

The study was sponsored by Aethera Corp., which provided equipment, discounts, travel expenses, a research grant, and honoraria to Dr. Gold.