

Photo at left shows a patient before treatment with the photopneumatic device. Photo at right shows improvement of the patient's acne after receiving four treatments over an interval of 3 weeks.



PHOTOS COURTESY DR. MICHAEL GOLDI/TENNESSEE CLINICAL RESEARCH CENTER

BRIEF SUMMARY OF PRESCRIBING INFORMATION

extina[®]
(ketoconazole) Foam, 2%

For topical use only Rx only

INDICATIONS AND USAGE

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

CONTRAINDICATIONS

None

WARNINGS 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 propane/butane, 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

Adverse Reactions	Extina Foam N = 672 n (%)	Vehicle Foam N = 497 n (%)
Subjects with an Adverse Reaction	188 (28%)	122 (25%)
Application site burning	67 (10%)	49 (10%)
Application site reaction	41 (6%)	24 (5%)

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

Dermal Safety Studies

In a photoallergenicity study, 9 of 53 subjects (17%) had reactions during the challenge period at both the irradiated and non-irradiated 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 (syndactylia and oligodactylia) in the rat when given orally in the diet at 80 mg/kg/day (4.8 times the maximum expected human topical dose based on a mg/m² comparison, assuming 100% absorption from 8 g of foam). However, these effects may be partly related to maternal toxicity, which was also observed at this dose level. [See *Pharmacokinetics*]

No reproductive studies in animals have been performed with Extina Foam. There are no adequate and well-controlled studies of Extina Foam in pregnant women.

Extina Foam should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers

It is not known whether Extina Foam administered topically could result in sufficient systemic absorption to produce detectable quantities in breast milk. Because many drugs are excreted 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.

Of the 672 subjects treated with Extina Foam in the clinical trials, 44 (7%) were from 12 to 17 years of age. [See *Clinical Studies*]

Geriatric Use

Of the 672 subjects treated with Extina Foam in the clinical trials, 107 (16%) were 65 years and over.

NONCLINICAL TOXICOLOGY Carcinogenesis, Mutagenesis, and Impairment of Fertility

Long-term animal studies have not been performed to evaluate the carcinogenic or photo-carcinogenic potential of Extina Foam.

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 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.

At oral dose levels of 75 mg/kg/day (4.5 times the expected topical human dose in mg/m²), ketoconazole impaired reproductive performance and fertility when administered to male rats (increased abnormal sperm, decreased sperm motility and decreased pregnancy in mated females).

Manufactured for Stiefel Laboratories, Inc.
Coral Gables, FL 33134 USA

Extina and Stiefel are registered trademarks, owned by Stiefel Laboratories, Inc.

U.S. Patent Pending

© 2008 Stiefel Laboratories, Inc.

802650-0707

Device Uses Light, Vacuum To Improve Acne Lesions

BY SHARON WORCESTER

Southeast Bureau

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

The recently approved Aesthera 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 pustular 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.

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

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.

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 Aesthera Corp., which provided equipment, discounts, travel expenses, a research grant, and honoraria to Dr. Gold. ■