A 56-year-old Caucasian male presented to the Drexel University department of dermatology in 1998 with two large, linear ulcerations on his left cheek. These ulcerations extended along almost his entire jaw line (Figure 1). Through questioning and physical exam it was determined that these ulcerations were of factitial origin, caused by repetitive plucking and attempted unearthing of hairs on the patient’s face. The patient had a long-standing psychiatric history and had been treated with a host of behavioral modification and oral psychiatric modifiers without improvement in his compulsive behavior. Ten years ago, his ulceration was treated by plastic surgery with a flap-repair that was subsequently destroyed via the patient’s self-mutilation. Over the years multiple topical and intralesional steroids were attempted in the treatment of these ulcers without significant improvement.

Given that the etiology of these ulcers was determined to result from a fixation on plucking of hairs on his cheek, laser hair removal with the long pulse 1064nm Neodymium Yttrium Aluminum Garnet (Nd/YAG) laser (Cynosure® Elite™) was offered and accepted by the patient as a potential treatment for his condition in 2009. After the first treatment the patient reported a decrease in the amount of hair that he desired to pick. The ulcerations also began to clinically improve with reduction in size and depth. A total of nine laser sessions were administered with near-complete removal of hair along the border and interior of the ulceration. Resolution of the ulceration was noted and the patient reported a decrease in the desire to pick at his own skin (Figure 2).

Discussion

Factitial dermatitides can be extraordinarily difficult to treat given their inherent multifactorial etiology. Psychiatric disturbances drive patients to inflict cutaneous damage upon themselves, and thus both the physical and mental manifestations of the disease must be treated. Unfortunately, the psychiatric
Atralin (tretinoin) gel 0.05%

BRIEF SUMMARY

(prescription insert for full prescribing information)

For topical use only.

INDICATIONS AND USAGE

Atralin Gel is a retinoid indicated for topical treatment of acne vulgaris. The safety and efficacy of the use of this product in the treatment of any of the disorders has not been evaluated.

CONTRAINDICATIONS

None

WARNINGS AND PRECAUTIONS

Skin Irritation

The skin of certain individuals may become dry, red, or irritated while using Atralin Gel. If the degree of irritation warrants, patients should be directed to temporarily reduce the amount or frequency of application of the medication, discontinue use temporarily, or discontinue use altogether. Efficacy at reduced frequencies of application has not been established. If a reaction suggesting sensitivity occurs, use of the medication should be discontinued. Mild to moderate skin dryness may also be experienced. If so, use of an appropriate moisturizer during the day may be helpful.

Tretinoin has been reported to cause severe irritation on eczematous or sunburned skin and should be used with caution in patients with these conditions.

Topical-Over-the-counter acne preparations, concomitant topical medications, medicated cleansers, topical products with alcohol or astringents, when used with Atralin Gel, should be used with caution [see Drug Interactions (7)].

Ultrasound and Environmental Exposure

Unprotected exposure to sunlight, including suntans, should be minimized when using the Atralin Gel. Patients who normally experience high levels of sun exposure, and those with inherent sensitivity to sun, should be warned to exercise caution. Use of sunscreen products at least SPF 15 and protective clothing over treated areas is recommended when exposure cannot be avoided.

Weather extremes, such as wind or cold, also may be irritating to patients under treatment with tretinoin.

Fish Allergies

Atralin Gel contains soluble fish proteins and should be used with caution in patients with known sensitivity or allergy to fish. Patients who develop pruritus or urticaria should contact their health care provider.

ADVERSE REACTIONS

Clinical Studies Experience

Because clinical trials are conducted under prescribed conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared with rates in the clinical trials of another drug and may not reflect the rates observed in practice.

In two randomized, controlled trials, 674 subjects received treatment for up to 12 weeks with Atralin Gel [see Clinical Studies (14)]. In these studies, 50% of the subjects who were treated with Atralin Gel reported one or more adverse reactions: 30% of the subjects reported treatment-related adverse reactions. In the vehicle group, 21% of the 467 randomized subjects reported at least one adverse reaction; 5% of the subjects reported events that were treatment-related. There were no serious, treatment-related adverse reactions reported by subjects in any of the treatment groups.

Selected adverse reactions that occurred in at least 1% of subjects in the two studies combined, are shown in Table 1 (below). Most skin-related adverse reactions first appeared during the first two weeks of treatment with Atralin Gel, and the incidence for skin-related adverse reactions peaks around the second and third week of treatment. In some subjects the skin-related adverse reactions persist throughout the treatment period.

Table 1. Number of Subjects with Selected Adverse Reactions (Occurring in At Least 1% of Subjects)

<table>
<thead>
<tr>
<th>Event</th>
<th>Atralin Gel (n = 674)</th>
<th>Vehicle Gel (n = 467)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dry Skin</td>
<td>109 (16%)</td>
<td>8 (2%)</td>
</tr>
<tr>
<td>Peeling/Scaling/Flaking Skin</td>
<td>78 (12%)</td>
<td>7 (1%)</td>
</tr>
<tr>
<td>Skin Burring Sensation</td>
<td>53 (8%)</td>
<td>8 (2%)</td>
</tr>
<tr>
<td>Erythema</td>
<td>47 (7%)</td>
<td>1 (1%)</td>
</tr>
<tr>
<td>Pruritus</td>
<td>11 (2%)</td>
<td>3 (1%)</td>
</tr>
<tr>
<td>Pain of Skin</td>
<td>7 (1%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Sunburn</td>
<td>7 (1%)</td>
<td>3 (1%)</td>
</tr>
</tbody>
</table>

DRUG INTERACTIONS

When treating the Atralin Gel, caution should be exercised with the use of concomitant topical medications, medicated or abrasive soaps and cleansers, products that have a strong drying effect, and products with high concentrations of alcohol, astringents, spices, or lime. Particular caution should be exercised with the concomitant use of topical over-the-counter acne preparations containing benzoyl peroxide, salicylic acid, or other agents. Allow the effects of such preparations to subside before use of Atralin Gel is begun.

USE IN SPECIFIC POPULATIONS

Pregnancy

Pregnancy Category C.

There are no well-controlled trials in pregnant women treated with Atralin Gel. Atralin Gel should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Atralin Gel at doses of 0.3 and 1 g/g day was tested for maternal and developmental toxicity in pregnant Sprague-Dawley rats by dermal application. The dose of 1 g/g day was approximately 4 times the clinical dose assuming 100% absorption and based on body surface area comparison. Nonteratogenic effects on fetuses: Increased skeletal variation occurred at all doses; dose-related increases in embryolethality and abortion also were reported. Similar results have also been reported in pellagrous macaque.

Topical tretinoin in a different formulation has generated equivocal results in animal teratogenicity tests. There is evidence for teratogenicity (shortened or kinked tail) of topical tretinoin in Wistar rats at doses greater than 7 mg/kg/day (approximately 8 times the clinical dose assuming 100% absorption and based on body surface area comparison). Anomalies (humans; short tail, bent 6%, or palatal incompleteness coded 14%) have also been reported when 10 mg/kg/day (approximately 150 times the clinical dose assuming 100% absorption and based on body surface area comparison) was topically applied. Supernumerary ribs have been a consistent finding in rats when dams were treated topically or orally with retinoids.

With widespread use of any drug, a small number of birth defects reports associated temporally with the administration of the drug would be expected by chance alone.

Cases of temporally associated congenital malformations have been reported with use of other topical tretinoin products. The significance of these spontaneous reports in terms of risk to the fetus is not known.

Nonteratogenic effects on fetuses: Oral tretinoin has been shown to be fetotoxic in rats when administered in doses 20 times the clinical dose based on a body surface area comparison. Topical tretinoin has been shown to be fetotoxic in rabbits when administered in doses 5 times the clinical dose based on a body surface area comparison.

Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Atralin Gel is administered to a nursing woman.

Pediatric Use

Safety and effectiveness in children below the age of 10 have not been established.

A total of 201 pediatric subjects (aged 10 to 16 years), treated with Atralin Gel were enrolled into the two clinical studies. Across these two studies, comparable safety and efficacy were observed between pediatric and adult subjects.

Geriatric Use

Safety and effectiveness in a geriatric population have not been established.

Clinical studies of Atralin Gel did not include any subjects over age 65 to determine the safety and effectiveness of the medication in this age group. Safety and effectiveness in a geriatric population have not been established.

In these studies, 50% of the treatment-related adverse reactions reported by subjects in any of the treatment groups. Selected adverse reactions that occurred in at least 1% of subjects in the two studies combined, are shown in Table 1 (below). Most skin-related adverse reactions first appeared during the first two weeks of treatment with Atralin Gel, and the incidence for skin-related adverse reactions peaks around the second and third week of treatment. In some subjects the skin-related adverse reactions persist throughout the treatment period.

The authors have no relevant financial interests.