**8.3 Nursing Mothers**

- Patients who are nursing or plan to nurse should not use Atralin Gel due to the potential for serious adverse effects in breastfeeding infants or to the risk of maternal or developmental toxicity in pregnant females.

**8.1 Pregnancy**

- Patients who are pregnant or plan to become pregnant should not use Atralin Gel due to the potential for serious adverse effects in breastfeeding infants or to the risk of maternal or developmental toxicity in pregnant females.

**6.1 Clinical Trials Experience**

- Patients who are allergic to fish. Atralin contains fish proteins.

**• Apply Atralin 1 time a day before bedtime.
• Use Atralin exactly as your healthcare provider prescribed for purposes of treating acne.
• Use only the amount prescribed by your healthcare provider for purposes of treating acne.
• Treat all the affected skin areas. Generically Atralin Gel is for use only on skin areas that are affected. See full prescribing information for details.

**ADVERSE REACTIONS**

There are no significant differences observed in the safety profile of Atralin Gel compared to tretinoin (tretinoin) Gel, 0.05%. Atralin is a retinoid indicated for topical treatment of acne vulgaris.

**6.2 Postmarketing Experience**

- Patients who are allergic to fish. Atralin contains fish proteins.

**2.1 Mechanism of Action**

- Patients who are allergic to fish. Atralin contains fish proteins.

**5.3 Fish Allergies**

- Patients who are allergic to fish. Atralin contains fish proteins.

**5.2 Ultraviolet Light and Environmental Exposure**

- Patients who are allergic to fish. Atralin contains fish proteins.

**5.1 Patient Information**

- Patients who are allergic to fish. Atralin contains fish proteins.

**2.1 Mechanism of Action**

- Patients who are allergic to fish. Atralin contains fish proteins.

**11 DESCRIPTION**

- Patients who are allergic to fish. Atralin contains fish proteins.

**10.2 Impairment of Fertility**

- Patients who are allergic to fish. Atralin contains fish proteins.

**12.1 Mechanism of Action**

- Patients who are allergic to fish. Atralin contains fish proteins.

**12.4 Overdosage**

- Patients who are allergic to fish. Atralin contains fish proteins.

**2.4 Long-term Use**

- Patients who are allergic to fish. Atralin contains fish proteins.

**2.3 Short-term Use**

- Patients who are allergic to fish. Atralin contains fish proteins.

**2.2 Long-term Use**

- Patients who are allergic to fish. Atralin contains fish proteins.

**2.1 Mechanism of Action**

- Patients who are allergic to fish. Atralin contains fish proteins.

**2.4 Long-term Use**

- Patients who are allergic to fish. Atralin contains fish proteins.

**2.3 Short-term Use**

- Patients who are allergic to fish. Atralin contains fish proteins.

**2.2 Long-term Use**

- Patients who are allergic to fish. Atralin contains fish proteins.

**2.1 Mechanism of Action**

- Patients who are allergic to fish. Atralin contains fish proteins.

**2.4 Long-term Use**

- Patients who are allergic to fish. Atralin contains fish proteins.

**2.3 Short-term Use**

- Patients who are allergic to fish. Atralin contains fish proteins.

**10.2 Impairment of Fertility**

- Patients who are allergic to fish. Atralin contains fish proteins.

**10.1 General Information**

- Patients who are allergic to fish. Atralin contains fish proteins.

**5.1 Patient Information**

- Patients who are allergic to fish. Atralin contains fish proteins.

**10.2 Impairment of Fertility**

- Patients who are allergic to fish. Atralin contains fish proteins.

**11 DESCRIPTION**

- Patients who are allergic to fish. Atralin contains fish proteins.

**10.2 Impairment of Fertility**

- Patients who are allergic to fish. Atralin contains fish proteins.

**5.1 Patient Information**

- Patients who are allergic to fish. Atralin contains fish proteins.

**10.2 Impairment of Fertility**

- Patients who are allergic to fish. Atralin contains fish proteins.

**5.1 Patient Information**

- Patients who are allergic to fish. Atralin contains fish proteins.

**10.2 Impairment of Fertility**

- Patients who are allergic to fish. Atralin contains fish proteins.

**5.1 Patient Information**

- Patients who are allergic to fish. Atralin contains fish proteins.

**10.2 Impairment of Fertility**

- Patients who are allergic to fish. Atralin contains fish proteins.

**5.1 Patient Information**

- Patients who are allergic to fish. Atralin contains fish proteins.
13. PHARMACODYNAMICS
The mechanism of action of topical retinoic acid is well understood. Clinical effects of retinoic acid are mediated through the binding of retinoic acid to specific retinoic acid receptors located in both the cytosol and nucleus, which act to modify gene expression, subsequent protein synthesis, and epithelial cell function.

14. CLINICAL TRIALS
14.1 Clinical Studies
A non-comparative trial of 6 weeks duration in which subjects were randomized to receive either 0.05% tretinoin gel or vehicle was conducted in 25 adult acne patients. The primary outcome measure was Global Severity Score. Subjects were instructed to apply a thin, even layer of Atralin Gel, 0.05% once daily to facial skin areas that are most severely affected by acne vulgaris. One non-randomized clinical trial evaluated the efficacy of Atralin Gel, 0.05% in the treatment of photodamage and actinic keratosis in 15 patients with facial wrinkles. The study was conducted in 16 subjects treated with 0.05% tretinoin gel or vehicle. The primary outcome measures were global facial wrinkling and tactile wrinkle depth.

15. ADVERSE REACTIONS
15.1 General Adverse Reactions
Adverse reactions reported during clinical trials and other sources of post-marketing experience are listed below by body system and by occurrence order from most frequently reported to least frequently reported.

16. HOW SUPPLIED/STORAGE AND HANDLING
Atralin Gel, 0.05% is supplied as a light yellow to off-white, opaque gel for topical application in 45 g tubes (NDC 13548-070-45). Each gram of Atralin Gel, 0.05% contains:

Tretinoin (Atralin Gel) 3 mg/g

Other components of this formulation are benzyl alcohol, butylated hydroxytoluene, carbomer 940, ethylparaben, fish collagen hydrolyzates, glycerin, iso-butyl paraben, methylparaben, octoxynol 9, propylene glycol, purified water, sodium hydroxide, and isosorbide.

Manufactured for:
Valmont Pharmaceuticals North America LLC
Bridgewater, NJ 08807
or
DPT Laboratories, Ltd
San Antonio, TX 78215
For more information: call 1-800-323-4076.
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