FULL PRESCRIBING INFORMATION

INDICATIONS AND USAGE

• To treat acne vulgaris. (1)

DOSAGE FORMS AND STRENGTHS

0.05% gel, 0.1% gel, and 0.01% ointment.

WARNINGS AND PRECAUTIONS

• Avoid use in children under 10 years of age. (1)

CONTRAINDICATIONS

• Atralin Gel may cause sunburn. Do not use near eyes, mouth, nasal creases, or mucous membranes. (2)

ADVERSE REACTIONS

• The most common adverse reactions (incidence ≥5%) with Atralin Gel are dry skin, peeling/scaling of skin, skin irritation, and erythema. (1)

PREGNANCY

• Atralin Gel should not be used in women who are pregnant or planning to become pregnant. (5.3)

• Atralin Gel should be kept away from the eyes, mouth, nasal creases, and mucous membranes. (2)

• Use sunscreen of at least SPF 15 and protective clothing during treatment with Atralin. (5.3)

• Oral inactivation has been shown to be effective in rats, mice, rabbits, hamsters, and guinea pigs. (20001418A)

CLINICAL PHARMACOLOGY

• Atralin Gel is a retinoid indicated for topical treatment of acne vulgaris. (1)

PATIENT COUNSELING INFORMATION

• Atralin will harm your unborn baby. (5.3)

• Atralin Gel contains soluble fish proteins and should be used with caution in patients allergic to fish. (20001418A)

• Atralin Gel should be applied once daily, before bedtime, to the skin where acne lesions occur. (1)

CLINICAL STUDIES

• Temporary hyper- or hypopigmentation has been reported with repeated application of Atralin Gel. (5.3)

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Topical tretinoin in a different formulation has generated equivocal results in effects in age, gender, or race subgroups.

The majority of patients in these studies were approximately 52% female, 48% male, and were 74% Caucasian, 15% Black or African American, and 1% other. Patients were between 12 and 75 years old. The mean age of patients varied from 31 to 50 years across different studies. Approximately 85% of patients were employed, and 70% were enrolled in the United States. Based on self-reported skin type, 66% were classified as normal/oily, 13% oily, 11% dry, 5% combination, and 5% very dry. The majority of patients were of Caucasian ancestry. Approximately 80% of patients had mild to moderate acne vulgaris.

17 PATIENT COUNSELING INFORMATION

Atralin should be used only as directed. Patients should consult their healthcare provider if they have any side effects that bothers you or that do not go away. These are not all of the side effects possible with Atralin.

10.1 How should I store Atralin?

Store Atralin at room temperature, 68°F to 77°F (20°C to 25°C). Protect from freezing.

Keep Atralin and all medicines out of the reach of children.

General information about the safe and effective use of Atralin

Medications are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use Atralin for Atralin unless you have been told to do so by your healthcare provider.

You can ask your pharmacist or healthcare provider for information about Atralin that is written for health professionals.

What are the ingredients of Atralin?

The inactive ingredients in Atralin are alcohol, glycerin, isopropylparaben, methylparaben, octoxynol 9, phenoxethanol, propylparaben, purified water, sodium hyaluronate, and trolamine.

The ingredients of Atralin were selected after thorough testing and evaluation to ensure a safe and effective topical drug product.

10.2 How do I use Atralin?

Each gram of Atralin, 0.05% contains 0.5 mg of tretinoin.

Other components of the formulation are: methyl alcohol, butylparaben, butylhydroxytoluene, customer homopropylene glycol, eucalyptus, fennel collodions, hyaluronic acid, light mineral oil, menthol, myristyl lactate, methylparaben, octoxynol 9, phenoxyethanol, propylparaben, purified water, sodium hyaluronate, and trolamine.

11 DESCRIPTION

Atralin Gel, 0.05% is a transcutaneous, opalescent gel containing 0.05% tretinoin, by weight for topical administration.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Topical tretinoin in a different formulation has generated equivocal results in effects in age, gender, or race subgroups.

Topical tretinoin is also available as an injectable preparation. The injectable form of tretinoin is manufactured by Atralin from the approved investigational investigational injectable tretinoin

12.2 Absorption

Studies in hairless albino mice with a different formulation suggested that concurrent exposure to tretinoin may enhance the tumorigenic potential of carcinogenic doses of UVB. With widespread use of any drug, a small number of birth defects may be expected by chance alone. Cases of temporally associated congenital anomalies were noted in a Patient Information leaflet. Do not use Atralin for Atralin unless you have been told to do so by your healthcare provider.

While not all possible side effects are listed, any side effect may become serious enough to require medical attention.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

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