ATRALIN- tretinoin gel
Bausch Health US, LLC

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use ATRALIN Gel safely and effectively. See full prescribing information for ATRALIN Gel.

ATRALIN® (tretinoin) Gel, 0.05%, for topical use
Initial U.S. Approval: 1973

INDICATIONS AND USAGE

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

DOSAGE AND ADMINISTRATION

- Apply a thin layer of Atralin Gel once daily, before bedtime, to skin where lesions occur. Keep away from eyes, mouth, nasal creases, and mucous membranes. (2)
- Atralin Gel is not for oral, ophthalmic, or intravaginal use. (2)

DOSAGE FORMS AND STRENGTHS

Gel, 0.05% (3)

CONTRAINDICATIONS

None (4)

WARNINGS AND PRECAUTIONS

- Atralin Gel should not be used on eczematous or sunburned skin due to potential for severe irritation. (5.1)
- Topical over-the-counter acne preparations, concomitant topical medications, medicated cleansers, topical products with alcohol or astringents: Use with caution, irritation may occur. (5.1)
- Avoid unprotected exposure to sunlight including sunlamps (UV light) when using Atralin Gel due to potential for increased photosensitization. Use sunscreen of at least SPF 15 and protective clothing during exposure. (5.2)
- Avoid use of Atralin Gel with weather extremes, such as wind or cold due to potential for increased irritation. (5.2)
- Use Atralin Gel with caution if allergic to fish due to potential for allergenicity to fish protein. Patients who develop pruritus or urticaria should contact their healthcare provider. (5.3)

ADVERSE REACTIONS

The most common adverse reactions (incidence ≥5%) with Atralin Gel are dry skin, peeling/scaling/flaking skin, skin burning sensation, and erythema. (6.1)
To report SUSPECTED ADVERSE REACTIONS, contact Bausch Health US, LLC at 1-800-321-4576 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.
See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.

Revised: 2/2024

FULL PRESCRIBING INFORMATION: CONTENTS*

* Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

Atralin Gel is indicated for topical treatment of acne vulgaris.

2 DOSAGE AND ADMINISTRATION

For topical use only. Not for oral, ophthalmic, or intravaginal use.

Atralin Gel should be applied once daily, before bedtime, to the skin where acne lesions appear, using a thin layer to cover the entire affected area. Atralin Gel should be kept away from the eyes, the mouth, paranasal creases, and mucous membranes. Application of excessive amounts of gel will not provide incremental efficacy.

Patients treated with Atralin Gel may use cosmetics, but the areas to be treated should be cleansed thoroughly before the medication is applied.

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

3 DOSAGE FORMS AND STRENGTHS

Gel, 0.05%

Each gram of Atralin Gel contains 0.5 mg (0.05%) tretinoin in a translucent to opaque, pale yellow topical gel.

4 CONTRAINDICATIONS

None.

5 WARNINGS AND PRECAUTIONS

5.1 Skin Irritation

The skin of certain individuals may become dry, red, or exfoliated 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 all together. 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.

To help limit skin irritation, patients must:

- wash the treated skin gently, using a mild, non-medicated soap, and pat it dry,
- avoid washing the treated skin too often and scrubbing the affected skin area, and
- avoid contact with the peels of limes.

5.2 Ultraviolet Light and Environmental Exposure

Unprotected exposure to sunlight, including sunlamps, should be minimized during the use of 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 of 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 tretinoin-treated skin.

5.3 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 healthcare provider.

6 ADVERSE REACTIONS

6.1 Clinical Trials Experience

Because clinical trials are conducted under prescribing 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.

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, 29% of the 487 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 trials combined are shown in Table 1 (below). Most skin-related adverse reactions first appear during the first two weeks of treatment with Atralin Gel, and the incidence rate for skin-related 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)

Event	Atralin Gel (N = 674)	Vehicle (N = 487)
Dry Skin	109 (16%)	8 (2%)
Peeling/Scaling/Flaking Skin	78 (12%)	7 (1%)
Skin Burning Sensation	53 (8%)	8 (2%)
Erythema	47 (7%)	1 (<1%)
Pruritus	11 (2%)	3 (1%)
Pain of Skin	7 (1%)	0 (0%)
Sunburn	7 (1%)	3 (1%)

6.2 Postmarketing Experience

The following adverse reactions have been identified during post-approval use of Atralin Gel. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Temporary hyper- or hypopigmentation has been reported with repeated application of tretinoin.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

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 0.1, 0.3 and 1 g/kg/day was tested for maternal and

developmental toxicity in pregnant Sprague-Dawley rats by dermal application. The dose of 1 g/kg/day was approximately four times the clinical dose assuming 100% absorption and based on body surface area comparison. Possible tretinoin-associated teratogenic effects (craniofacial abnormalities [hydrocephaly], asymmetrical thyroids, variations in ossification, and increased supernumerary ribs) were noted in the fetuses of Atralin Gel-treated animals. These findings were not observed in control animals. Other maternal and reproductive parameters in the Atralin Gel-treated animals were not different from control. For purposes of comparison of the animal exposure to human exposure, the clinical dose is defined as 2 g of Atralin Gel applied daily to a 50 kg person.

Oral tretinoin has been shown to be teratogenic in rats, mice, rabbits, hamsters and nonhuman primates. Tretinoin was teratogenic in Wistar rats when given orally in doses greater than 1 mg/kg/day (approximately eight times the clinical dose based on body surface area comparison). In the cynomolgus monkey, fetal malformations were reported for doses of 10 mg/kg/day, but none were observed at 5 mg/kg/day (approximately 80 times the clinical dose based on body surface area comparison), although increased skeletal variations were observed at all doses. Dose-related increases in embryolethality and abortion also were reported. Similar results have also been reported in pigtail macaques.

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 1 mg/kg/day (approximately eight times the clinical dose assuming 100% absorption and based on body surface area comparison). Anomalies (humerus: short 13%, bent 6%, os parietal incompletely ossified 14%) have also been reported when 10 mg/kg/day (approximately 160 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 defect 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 body surface area comparison. Topical tretinoin has been shown to be fetotoxic in rabbits when administered in doses eight times the clinical dose based on body surface area comparison.

8.3 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.

8.4 Pediatric Use

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

A total of 381 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.

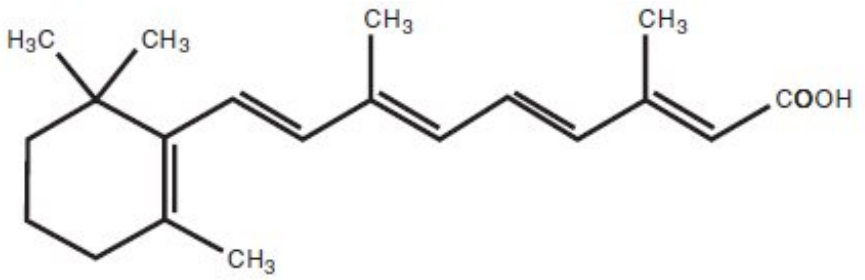
8.5 Geriatric Use

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 whether they respond differently from younger subjects.

11 DESCRIPTION

Atralin (tretinoin) Gel, 0.05% is a translucent to opaque, pale yellow gel containing 0.05% tretinoin, by weight for topical administration.

Chemically, tretinoin is all-*trans*-retinoic acid, also known as (all-*E*)-3,7-dimethyl-9-(2,6,6-trimethyl-1-cyclohexen-1-yl)-2,4,6,8-nonatetraenoic acid. It is a member of the retinoid class of compounds, and a metabolite of Vitamin A. Tretinoin has a molecular weight of 300.44, a molecular formula of $C_{20}H_{28}O_2$ and the following structure:



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

Other components of this formulation are benzyl alcohol, butylparaben, butylated hydroxytoluene, carbomer homopolymer Type C, ethylparaben, fish collagen hydrolyzates, glycerin, isobutylparaben, methylparaben, octoxynol 9, phenoxyethanol, propylparaben, purified water, sodium hyaluronate, and trolamine. The contribution to efficacy of individual components of the vehicle has not been evaluated.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Tretinoin is a metabolite of Vitamin A that binds with high affinity to specific retinoic acid receptors located in both the cytosol and nucleus, but cutaneous levels of tretinoin in excess of physiologic concentrations occur following application of a tretinoin-containing topical drug product.

Although tretinoin activates three members of the retinoid acid (RAR) nuclear receptors (RARα, RARβ, and RARγ) which act to modify gene expression, subsequent protein synthesis, and epithelial cell growth and differentiation, it has not been established

whether the clinical effects of tretinoin are mediated through activation of retinoic acid receptors, other mechanisms, or both.

Although the exact mode of action of tretinoin is unknown, current evidence suggests that topical tretinoin decreases cohesiveness of follicular epithelial cells with decreased microcomedo formation. Additionally, tretinoin stimulates mitotic activity and increased turnover of follicular epithelial cells causing extrusion of the comedones.

12.3 Pharmacokinetics

In two studies, the plasma levels of tretinoin and its major metabolites (13-cis-retinoic acid and 4-oxo-13-cis-retinoic acid) were investigated in a total of 14 patients (age: 13 – 25 years) with severe acne, who applied 4 g ± 0.5 g (range 3.5 g – 4.5 g) of Atralin Gel once daily to face, back and chest, as compared to a mean of 0.71 g (range of 0.07 – 3.71 g) applied in the controlled clinical trials. Blood samples were taken at baseline and immediately prior to treatment on Days 1, 5, 10 and 14. On Day 14, the final study day, samples also were taken 1, 2, 4, 6, 8, 10, 12, 16, and 24 hours post-treatment.

The plasma concentrations of tretinoin and its metabolites could be measured (LOQ = 0.5 ng/mL for all three analytes) in all patients at all time points. The range of plasma concentrations of tretinoin and its metabolites, 13-cis-retinoic acid and all-trans-4-oxo-retinoic acid at baseline and after multiple once-daily applications of Atralin Gel, 0.05% for 14 days are given in Table 2 (below). Although some patients had increased concentrations of tretinoin or its metabolites over baseline values, no consistent increase in these concentrations were observed across patients.

Table 2: Concentrations of Active and Metabolites at Baseline and at Day 14 After Exposure to Atralin Gel, 0.05%

Compound	Baseline Concentration Range (ng/mL)	Day 14 Concentration Range (ng/mL)
Tretinoin	0.68-1.62	0.69-2.88
13-cis-retinoic acid	0.67-1.79	0.51-2.26
4-oxo-13-cis-retinoic acid	0.82-5.92	0.59-6.96

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

A 2-year dermal mouse carcinogenicity study was initiated with topical administration of 0.005%, 0.025% and 0.05% Atralin Gel. Although no drug-related tumors were observed in surviving animals, the irritating nature of the drug product precluded daily dosing, confounding data interpretation and reducing the biological significance of these results.

Studies in hairless albino mice with a different formulation suggest that concurrent exposure to tretinoin may enhance the tumorigenic potential of carcinogenic doses of UVB and UVA light from a solar simulator. This effect was confirmed in a later study in pigmented mice, and dark pigmentation did not overcome the enhancement of photocarcinogenesis by 0.05% tretinoin. Although the significance of these studies to

humans is not clear, patients should minimize exposure to sunlight or artificial ultraviolet irradiation sources.

The genotoxic potential of tretinoin was evaluated in an *in vitro* bacterial reversion test, an *in vitro* chromosomal aberration assay in human lymphocytes and an *in vivo* rat micronucleus assay. All tests were negative.

In dermal fertility studies of another tretinoin formulation in rats, slight (not statistically significant) decreases in sperm count and motility were seen at 0.5 mg/kg/day (3 mg/m^2, approximately four times the clinical dose based on body surface area comparison), and slight (not statistically significant) increases in the number and percent of nonviable embryos in females treated with 0.25 mg/kg/day and above (1.5 mg/m^2, approximately two times the clinical dose based on body surface area comparison) were observed.

14 CLINICAL STUDIES

The safety and efficacy of Atralin Gel used once daily before bedtime for the treatment of mild to moderate acne vulgaris were assessed in two 12-week prospective, multicenter, randomized, controlled trials. Subjects in these two trials ranged from 10 to 65 years of age, were approximately 52% female, 48% male, and were 74% Caucasian, 15% Black or African American, 3% Asian, and 8% Other.

Efficacy results at Week 12 are presented in Table 3. Success on the 6-point Global Severity Score is defined as a score of 0 (clear) or 1 (very mild). In Trial 2, subjects were also required to have at least two grades reduction from baseline for success. 'Very mild' acne is defined as: *skin almost clear; rare non-inflammatory lesions present, with rare non-inflamed papules (papules may be hyperpigmented, though not pink-red, less than 4 lesions).* The database was not large enough to assess whether there were differences in effects in age, gender, or race subgroups.

Table 3: Efficacy Results at Week 12 in Trials 1 and 2

Trial 1	**Atralin Gel (N=375)**	**Vehicle (N=185)**
Global Severity Score Success*	78 (21%)	23 (12%)
Non-Inflammatory Facial Lesions		
Mean Baseline Count	50.7	52.4
Mean Absolute Reduction	21.8	10.3
Mean Percent Reduction	43%	21%
Inflammatory Facial Lesions		
Mean Baseline Count	23.4	23.9
Mean Absolute Reduction	9.7	5.8
Mean Percent Reduction	41%	26%
Total Facial Lesions		
Mean Baseline Count	74.1	76.3
Mean Absolute Reduction	31.4	16.1

Mean Percent Reduction	43%	22%
Trial 2	**Atralin Gel (N=299)**	**Vehicle (N=302)**
Global Severity Score Success†	69 (23%)	42 (14%)
Non-Inflammatory Facial Lesions		
Mean Baseline Count	51.9	52.7
Mean Absolute Reduction	18.7	10.8
Mean Percent Reduction	37%	20%
Inflammatory Facial Lesions		
Mean Baseline Count	22.9	23.4
Mean Absolute Reduction	7.0	4.0
Mean Percent Reduction	30%	17%
Total Facial Lesions		
Mean Baseline Count	74.8	76.1
Mean Absolute Reduction	25.7	14.7
Mean Percent Reduction	35%	19%

* Success was defined as 0 (clear) or 1 (very mild)
† Success was defined as 0 (clear) or 1 (very mild) with at least two grades reduction from baseline

16 HOW SUPPLIED/STORAGE AND HANDLING

Atralin (tretinoin) Gel, 0.05% is a translucent to opaque, pale yellow topical gel and available as:

- 45 g tube NDC 13548-070-45

Storage and Handling: Store at controlled room temperature 20° to 25°C (68° to 77°F) with excursions permitted between 15° to 30°C (59° to 86°F). Protect from freezing. Keep out of reach of children.

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Patient Information).

Instruct patients to clean the affected areas with an appropriate cleanser before applying Atralin Gel.

Patients may use moisturizers that are noncomedogenic and should avoid products that could be drying or irritating.

Patients may also wear cosmetics while being treated with Atralin Gel; however, they should be instructed to remove the cosmetics and clean the area thoroughly before applying Atralin Gel.

Warn patients of the drying and irritation effects often seen during treatment. Continue use of the medication if these effects are tolerable.

Caution patients against application of Atralin Gel around the eyes, mouth, paranasal creases, and mucous membranes as the skin is especially prone to irritation.

Minimize exposure to sunlight, including sunlamps. Recommend the use of sunscreen products and protective apparel (e.g., hat) when exposure cannot be avoided.

Distributed by:

Bausch Health US, LLC

Bridgewater, NJ 08807 USA

Manufactured by:

Bausch Health Companies Inc.

Laval, Quebec H7L 4A8, Canada

9549701

Patient Information
Atralin® (A-truh-lin)
(tretinoin) Gel, 0.05%
for topical use

Important information: Atralin is for use on skin only. Do not get Atralin in your mouth, eyes, vagina, or the corners of your nose.

What is Atralin?

Atralin is a prescription medicine used on the skin (topical) to treat acne. Acne is a condition in which the skin has blackheads, whiteheads, and other pimples.

It is not known if Atralin is safe and effective in children under 10 years of age.

What should I tell my healthcare provider before using Atralin?

Before using Atralin, tell your healthcare provider about all of your medical conditions, including if you:

- are allergic to fish. Atralin contains fish proteins. Tell your healthcare provider if you get hives or itching during treatment with Atralin.
- have a skin condition called eczema.
- have a sunburn.
- are pregnant or plan to become pregnant. It is not known if Atralin will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if Atralin passes into your breast milk.

Tell your healthcare provider about all the medicines you take, including prescription and

over-the-counter medicines, vitamins, herbal supplements, and any skin products that you use.

Especially tell your healthcare provider if you use any other medicines to treat your acne, including medicated cleansers or soaps. Using other topical acne products may increase the irritation of your skin when used with Atralin.

How should I use Atralin?

- Use Atralin exactly as your healthcare provider tells you to use it.
- Before you apply Atralin, gently wash the affected skin area with a mild, non-medicated soap. Rinse and pat your skin dry.
- Apply Atralin 1 time a day before bedtime.
- Apply a thin layer of Atralin to cover the affected skin areas. Gently rub Atralin into your skin.
- Do not use more Atralin than you need to cover the affected area and do not apply Atralin more than 1 time a day. Using too much Atralin may irritate or increase the irritation of your skin, and will not give faster or better results.
- You may use moisturizers and cosmetics.

What should I avoid while using Atralin?

- Avoid washing your skin too often and scrubbing the affected skin area.
- You should avoid sunlamps, tanning beds, and ultraviolet light during treatment with Atralin.
- Minimize exposure to sunlight.
- If you have to be in the sunlight or are sensitive to sunlight, use a sunscreen with a (SPF) sun protection factor of 15 or more and wear protective clothing, and a wide brimmed hat to cover the treated areas.
- If you do get sunburned, stop using Atralin until your skin has healed and is back to normal.
- Cold weather and wind may irritate skin treated with Atralin. Skin treated with Atralin may dry out or get wind burned more easily. Talk to your healthcare provider about ways to manage skin irritation.
- Avoid contact with the peels of limes.

What are the possible side effects of Atralin?

Atralin may cause skin irritation, including: skin dryness, burning, redness, excessive flaking or peeling. If you develop these symptoms, your healthcare provider may tell you to stop using Atralin for a while, decrease the number of times you apply Atralin, or completely stop treatment with Atralin. It is not known if Atralin is effective when used less than 1 time a day.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all of the side effects possible with Atralin.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

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

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use Atralin for a condition for which it was not prescribed. Do not give Atralin to other people, even if they have the same symptoms you have. It may harm them.

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

What are the ingredients of Atralin?

Active ingredient: tretinoin
Inactive ingredients: benzyl alcohol, butylparaben, butylated hydroxytoluene, carbomer homopolymer Type C, ethylparaben, fish collagen hydrolyzates, glycerin, isobutylparaben, methylparaben, octoxynol 9, phenoxyethanol, propylparaben, purified water, sodium hyaluronate, and trolamine.

Distributed by:

Bausch Health US, LLC

Bridgewater, NJ 08807 USA

Manufactured by:

Bausch Health Companies Inc.

Laval, Quebec H7L 4A8, Canada

For more information, call 1-800-321-4576.

This Patient Information has been approved by the U.S. Food and Drug Administration.

Rev. 02/2024 9549701

PRINCIPAL DISPLAY PANEL - 45 g Tube Carton

NDC 13548-070-45

Atralin®
(tretinoin) gel 0.05%

Rx only

Net Wt. 45 g

ATRALIN

tretinoin gel

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:13548-070
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Tretinoin (UNII: 5688UTC01R) (Tretinoin - UNII:5688UTC01R)	Tretinoin	0.05 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
benzyl alcohol (UNII: LKG8494WBH)	
butylparaben (UNII: 3QPI1U3FV8)	
butylated hydroxytoluene (UNII: 1P9D0Z171K)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	

ethylparaben (UNII: 14255EXE39)	
MARINE COLLAGEN, SOLUBLE (UNII: 8JC99XGU4W)	
glycerin (UNII: PDC6A3C0OX)	
isobutylparaben (UNII: 0QQJ25X58G)	
methylparaben (UNII: A2I8C7HI9T)	
octoxynol-9 (UNII: 7JPC6Y25QS)	
phenoxyethanol (UNII: HIE492ZZ3T)	
propylparaben (UNII: Z8IX2SC1OH)	
water (UNII: 059QF0KO0R)	
hyaluronate sodium (UNII: YSE9PPT4TH)	
trolamine (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13548-070-45	1 in 1 PACKAGE	07/26/2007	
1		45 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:13548-070-01	2 g in 1 TUBE; Type 0: Not a Combination Product	07/26/2007	06/30/2017

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA022070	07/26/2007	

Labeler - Bausch Health US, LLC (831922468)

Establishment

Name	Address	ID/FEI	Business Operations
Bausch Health Companies Inc.		245141858	MANUFACTURE(13548-070)

Revised: 2/2024 Bausch Health US, LLC