HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use Tretinoin Gel 0.05%* safely and effectively. See full prescribing information for Tretinoin Gel 0.05%*.

Tretinoin Gel 0.05%*

For topical use only
Initial U.S. Approval: 1973

----------INDICATIONS AND USAGE----------
Tretinoin Gel 0.05% is a retinoid indicated for topical treatment of acne vulgaris (1)
----------DOSAGE AND ADMINISTRATION----------
- Apply a thin layer of Tretinoin Gel 0.05% once daily, before bedtime, to skin where lesions occur. Keep away from eyes, mouth, nasal creases, and mucous membranes (2)
- Tretinoin Gel 0.05% is not for oral, ophthalmic, or intravaginal use (2).

----------DOSAGE FORMS AND STRENGTHS----------
0.05% gel in 20 g tubes (3)

----------CONTRAINDICATIONS----------
None (4)
----------WARNINGS AND PRECAUTIONS----------
- Tretinoin Gel 0.05% should not be used on eczematous or sunburned skin due to potential for severe irritation (5.1)
- Avoid unprotected exposure to sunlight when using Tretinoin Gel 0.05% due to potential for increased photosensitization. Use sunscreen of at least SPF 15 and protective clothing during exposure (5.2)
- Avoid use of Tretinoin Gel 0.05% with weather extremes, such as wind or cold due to potential for increased irritation (5.2)
- Use Tretinoin Gel 0.05% with caution if allergic to fish due to potential for allergenicity to fish protein. Patients who develop pruritus or urticaria should contact their health care provider (5.3)

----------ADVERSE REACTIONS----------
The most common adverse reactions (incidence ≥ 5%) with Tretinoin Gel 0.05% are dry skin, peeling/scaling/flaking skin, skin burning sensation, and erythema. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Valeant Pharmaceuticals North America at 1-800-556-1937 or FDA at 1 800-FDA-1088 or www.fda.gov/medwatch.
----------DRUG INTERACTIONS----------
- Topical over-the-counter acne preparations, concomitant topical medication, medicated cleansers, topical products with alcohol or astringents: Use with caution, irritation may occur. (7)

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling
Revised: 7/2007

FULL PRESCRIBING INFORMATION: CONTENTS*

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

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE
Tretinoin Gel 0.05% is a retinoid indicated for topical treatment of acne vulgaris.

1.1 Important Limitations of Use
The safety and efficacy of the use of this product in the treatment of any other disorders have not been evaluated.

2 DOSAGE AND ADMINISTRATION
Tretinoin Gel 0.05% should be applied once daily, before bedtime, to the skin where acne lesions appear, using a thin layer to cover the entire affected area. Tretinoin Gel 0.05% 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 Tretinoin Gel 0.05% may use cosmetics, but the areas to be treated should be cleansed thoroughly before the medication is applied.

3 DOSAGE FORMS AND STRENGTHS
0.05% weight/weight topical gel, in 20 gram tubes

4 CONTRAINDICATIONS
None

5 WARNINGS AND PRECAUTIONS
5.1 Skin Irritation
The skin of certain individuals may become dry, red, or exfoliated while using Tretinoin Gel 0.05%. 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.

Topical over-the-counter acne preparations, concomitant topical medication, medicated cleansers, topical products with alcohol or astringents, when used with Tretinoin Gel 0.05%, should be used with caution. *[see Drug Interactions (7)]*.

5.2 Ultraviolet Light and Environmental Exposure
Unprotected exposure to sunlight, including sunlamps, should be minimized during the use of Tretinoin Gel 0.05%. 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 patients under treatment with tretinoin.

5.3 Fish Allergies
Tretinoin Gel 0.05% 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.

6 ADVERSE REACTIONS
6.1 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 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 Tretinoin Gel 0.05% *[see Clinical Studies (14)]*. In these studies, 50% of the subjects who were treated with Tretinoin Gel 0.05% 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 studies combined, are shown in Table 1 (below). Most skin-related adverse reactions first appear during the first two weeks of treatment with Tretinoin Gel 0.05%, 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 persists throughout the treatment period.

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

Event	Tretinoin Gel 0.05% (n = 674)	Vehicle Gel (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%)

7 DRUG INTERACTIONS
When treating with Tretinoin Gel 0.05%, caution should be exercised with the use of concomitant topical medication, 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, sulfur, resorcinol, or salicylic acid. Allow the effects of such preparations to subside before use of Tretinoin Gel 0.05% is begun.

8 USE IN SPECIFIC POPULATIONS
8.1 Pregnancy
Pregnancy Category C. There are no well-controlled trials in pregnant women treated with Tretinoin Gel 0.05%. Tretinoin Gel 0.05% should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Tretinoin Gel 0.05% 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 4 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 Tretinoin Gel 0.05% treated animals. These findings were not observed in control animals. Other maternal and reproductive parameters in the Tretinoin Gel 0.05% 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 Tretinoin Gel 0.05% 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 8 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 8 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 a body surface area comparison. Topical tretinoin has been shown to be fetotoxic in rabbits when administered in doses 8 times the clinical dose based on a body surface area comparison.

8.3 Nursing Mothers
It is not known whether this drug is excreted in human milk. Because many

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Tretinoin Gel 0.05% may not be right for you. Tell your doctor about all of your health conditions, including if you:
- **are allergic to fish**
- **have a skin condition called eczema**
- **are pregnant or planning to become pregnant.** Tretinoin Gel 0.05% may harm your fetus (unborn baby).
- **are breastfeeding.** It is not known if Tretinoin Gel 0.05% passes into breast milk and to your baby.

Tell your doctor about all the medicines you take including prescription and nonprescription medicines, vitamins and herbal supplements. Some medicines can make your skin more sensitive to sunlight.

Know the medicines you take. Keep a list of your medicines with you to show your doctor. Your doctor will decide if you can use Tretinoin Gel 0.05% with your other medicines.

Tell your doctor about all of the skin products you use. Your doctor will tell you which skin products you can use with Tretinoin Gel 0.05%. You should avoid using skin products that can dry or irritate your skin because skin dryness and irritation are increased with Tretinoin Gel 0.05%. Skin products that can dry and irritate your skin include:

- products that contain alcohol, astringents, or spices
- acne medicines that contain benzoyl peroxide, sulfur, resorcinol, or salicylic acid
- medicated soap or skin cleansers

How should I use Tretinoin Gel 0.05%?

- Wash your skin with mild, non-medicated soap and dry your skin gently. Apply Tretinoin Gel 0.05% once a day before bedtime.
- Squeeze a small amount of Tretinoin Gel 0.05% (about the size of a pea) on your fingertip. Apply Tretinoin Gel 0.05%, using a thin layer to cover the entire affected area. Smooth Tretinoin Gel 0.05% gently into your skin.
- Do not put Tretinoin Gel 0.05%, near your mouth, eyes, on the corners of your nose, or on open sores. Spread Tretinoin Gel 0.05% away from these areas when putting Tretinoin Gel 0.05% on your skin.
- Do not use more Tretinoin Gel 0.05% than your doctor has prescribed. Do not use Tretinoin Gel 0.05% more often than your doctor has told you. Too much Tretinoin Gel 0.05% may irritate or increase the irritation of your skin, and will not give faster or better results.
- You can use a facial cream or lotion of SPF 15 or higher each morning after washing your face. Follow your doctor's advice because you need to use a cream or lotion that will not make your acne worse. You may use cosmetics with Tretinoin Gel 0.05%. However, clean your face before using cosmetics and remove cosmetics from your skin before using Tretinoin Gel 0.05%. Talk to your doctor about recommended cosmetics.
- You may not see improvement right away. Tretinoin Gel 0.05% may work better for some patients than for others.
- Once your acne is under control you should continue to use Tretinoin Gel 0.05% as your doctor instructs you to do.

What should I avoid while using Tretinoin Gel 0.05%?

- Spend as little time as possible in the sun. Use a daily sunscreen with a SPF 15 rating or higher, protective clothing, and a wide brimmed hat to protect you from sunlight. When outside, even on hazy days, areas treated with Tretinoin Gel 0.05% should be protected. Do not use sunlamps or tanning beds. Tretinoin Gel 0.05% may make you get sunburned more easily. If you do get sunburned, stop using Tretinoin Gel 0.05% until your skin is completely back to normal. Talk to your doctor about how to protect your skin if you must be in sunlight a lot.
- Avoid cold weather and wind as much as possible, and use clothing to protect you from the weather. Skin treated with Tretinoin Gel 0.05% may dry out or get wind burned more easily.

What are the possible side effects of Tretinoin Gel 0.05%?

The most common side effect with Tretinoin Gel 0.05% is skin irritation. This can include dry skin, burning, redness, excessive flaking or peeling. Some of these side effects may go away or bother you less after you have used Tretinoin Gel 0.05% for a few weeks. Tell your doctor if these side effects become a problem.

Your doctor may ask you to stop using Tretinoin Gel 0.05% for a while, change the amount of Tretinoin Gel 0.05% you are using, or have you use Tretinoin Gel 0.05% less than once a day.

These are not all the side effects possible with Tretinoin Gel 0.05%. For more information, ask your doctor or pharmacist.

How do I store Tretinoin Gel 0.05%?

Store Tretinoin Gel 0.05% at controlled room temperature 20° - 25°C (68° - 77°F) with excursions permitted between 15°-30°C (59°-86°F).

Protect from freezing.

Keep Tretinoin Gel 0.05% and all medicines out of the reach of children.

General Information about Tretinoin Gel 0.05%

Do not allow anyone else to use this medicine. Medicines are sometimes prescribed for conditions not mentioned in patient information leaflets. Do not use Tretinoin Gel 0.05% for a condition for which it was not prescribed by your doctor. Do not share Tretinoin Gel 0.05% with other people, even if they have the same condition you have. It may harm them.

What are the ingredients of Tretinoin Gel 0.05%?

Active ingredient: tretinoin
Inactive ingredients: benzyl alcohol, butyl paraben, butylated hydroxytoluene, carbomer 940, ethyl paraben, fish collagen hydrolyzates, glycerin, iso-butyl paraben, methylparaben, octoxynol 9, phenoxyethanol, propylparaben, purified water, sodium hyaluronate, and trolamine.

This leaflet gives the most important information about Tretinoin Gel 0.05%. For more information about Tretinoin Gel 0.05%, talk with your doctor. You can ask your doctor or pharmacist for the information about Tretinoin Gel 0.05% that is written for health professionals. You can also contact Valeant Pharmaceuticals by calling their toll-free number: 1-800-556-1937.

OBAGI® MEDICAL
A DIVISION OF VALEANT PHARMACEUTICALS

Distributed by:
OMP, Inc.
a division of Valeant Pharmaceuticals North America LLC
Long Beach, CA 90806

Patent No.: 5,670,547
Part No.: 140175
Rev. Date: 2/14

Manufactured by:
DPT LABORATORIES, LTD.
San Antonio, TX 78215

drugs are excreted in human milk, caution should be exercised when Tretinoin Gel 0.05% 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 Tretinoin Gel 0.05% were enrolled into the two clinical studies. Across these two studies, comparable safety and efficacy were observed between pediatric and adult subjects.

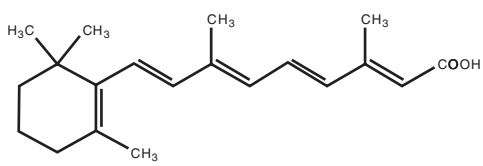
8.5 Geriatric Use

Safety and effectiveness in a geriatric population have not been established. Clinical studies of Tretinoin Gel 0.05% did not include any subjects over age 65 to determine whether they respond differently from younger subjects.

11 DESCRIPTION

Tretinoin Gel 0.05% is a translucent to opaque, pale yellow topical gel containing 0.05% tretinoin, by weight. Other components of this formulation are benzyl alcohol, butyl paraben, butylated hydroxytoluene, carbomer 940, ethyl paraben, fish collagen hydrolyzates, glycerin, iso-butyl paraben, methylparaben, octoxynol 9, phenoxyethanol, propylparaben, purified water, sodium hyaluronate, and trolamine.

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 family of compounds, and a metabolite of Vitamin A. Tretinoin has a molecular weight of 300.44. Tretinoin has the following structure:



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 (2) 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 Tretinoin Gel 0.05% 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 Tretinoin 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 Tretinoin 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

Carcinogenicity, photocarcinogenicity and mutagenicity testing of Tretinoin Gel 0.05% have not been performed in any species.

In a 91-week dermal study in which mice were administered 0.017% and 0.035% formulations of tretinoin in a different formulation, cutaneous squamous cell carcinomas and papillomas in the treatment area were observed in some female mice. These concentrations are near the tretinoin concentration of Tretinoin Gel 0.05%. A dose-related incidence of liver tumors in male mice was observed at those same doses. The maximum systemic doses associated with the administered 0.017% and 0.035% formulations are 0.5 and 1 mg/kg/day, (1.5 and 3 mg/m^2, respectively, approximately 2 and 4 times the clinical dose based on body surface area comparison). The biological significance of these findings is not clear because they occurred at doses that exceeded the dermal maximum tolerated dose (MTD) of tretinoin and because they were within the background natural occurrence rate for these tumors in this strain of mice. There was no evidence of carcinogenic potential when 0.025 mg/kg/day (0.075 mg/m^2 approximately 0.1 times the clinical dose, based on body surface area comparison) of tretinoin was administered topically to mice.

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 in 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 4 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 2 times the clinical dose based on body surface area comparison), were observed.

14 CLINICAL STUDIES

The safety and efficacy of Tretinoin Gel 0.05% used once daily before bedtime for the treatment of mild to moderate acne vulgaris were assessed in two 12-week prospective, multi-center, randomized, controlled studies. Subjects in these two studies 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 Study 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 Studies 1 and 2

Study 1	**Tretinoin Gel 0.05%**	**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%
Study 2	**Tretinoin Gel 0.05%**	**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 2 grades reduction from baseline

16 HOW SUPPLIED/STORAGE AND HANDLING

Tretinoin Gel 0.05% is available as:

- 20g tubes (NDC 62032-413-20)

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

17 PATIENT COUNSELING INFORMATION

[See FDA-Approved Patient Labeling (17.5)]

17.1 Pregnancy

Instruct female patients to inform the treating physician of any plans to become pregnant. If the patient becomes pregnant, discontinue use and inform the treating physician immediately. Tretinoin Gel 0.05% should be used in pregnancy only if the potential benefit justifies the potential risk to the fetus.

17.2 Skin Irritation

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

Caution patients against application of Tretinoin Gel 0.05% around the eyes, mouth, paranasal creases, and mucous membranes as this skin is especially prone to irritation.

17.3 Skin Care Regimen

Instruct patients to clean the affected areas with an appropriate cleanser before applying Tretinoin Gel 0.05%.

Patients may use moisturizers that are non-comedogenic, and should avoid products that could be drying or irritating.

Patients may also wear cosmetics while being treated with Tretinoin Gel 0.05%. However, they should be instructed to remove the cosmetics and clean the area thoroughly before applying Tretinoin Gel 0.05%.

17.4 Sun Exposure

Instruct patients to avoid direct exposure to the sun or sunlamps and to use sunscreen.

17.5 FDA-Approved Patient Labeling

Tretinoin Gel 0.05%

For Skin Use Only
Important: Not for mouth, eye, or vaginal use.

Read the patient information that comes with Tretinoin Gel 0.05% before you start using it and each time you get a refill. There may be new information. This leaflet does not take the place of talking with your doctor about your acne or treatment.

What is Tretinoin Gel 0.05%?

Tretinoin Gel 0.05% is a prescription medicine used on the skin to treat acne. Acne is a condition in which the skin has blackheads, whiteheads, and other pimples.