ADAPALENE- adapalene gel
Sandoz Inc.

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use ADAPALENE GEL safely and effectively. See full prescribing information for ADAPALENE GEL, 0.3%.

ADAPALENE Gel, 0.3% For topical use only
Initial U.S. Approval: 1996

INDICATIONS AND USAGE

Adapalene Gel, 0.3%, is a retinoid, indicated for the topical treatment of acne vulgaris in patients 12 years of age and older. (1)

DOSAGE AND ADMINISTRATION

Apply a thin film of adapalene gel, 0.3% to the entire face and any other affected areas of the skin once daily in the evening, after washing gently with a non-medicated soap. (2)
For topical use only. Not for ophthalmic, oral or intravaginal use. (2)

DOSAGE FORMS AND STRENGTHS

Each gram of Adapalene Gel USP, 0.3% contains 3 mg adapalene in an off-white aqueous gel. (3)

CONTRAINDICATIONS

Adapalene gel, 0.3% should not be administered to individuals who are hypersensitive to adapalene or any of the components in the gel vehicle. (4)

WARNINGS AND PRECAUTIONS

Ultraviolet Light and Environmental Exposure: Avoid exposure to sunlight and sunlamps. Wear sunscreen when sun exposure cannot be avoided (5.1). Erythema, scaling, dryness, and stinging/burning were reported with use of adapalene gel (5.2).

ADVERSE REACTIONS

The most frequently reported (≥1%) adverse reactions were dry skin, skin discomfort, pruritus, desquamation, and sunburn. (6.1)
To report SUSPECTED ADVERSE REACTIONS, contact Sandoz Inc. at 1-800-525-8747 or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch.*

DRUG INTERACTIONS

As adapalene gel has the potential to induce local irritation in some patients, concomitant use of other potentially irritating topical products (medicated or abrasive soaps and cleansers, soaps and cosmetics that have a strong drying effect, and products with high concentrations of alcohol, astringents, spices, or lime) should be approached with caution. Use with caution, especially when using preparations containing sulfur, resorcinol, or salicylic acid in combination with adapalene gel. (7)
See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.

Revised: 10/2019

FULL PRESCRIBING INFORMATION: CONTENTS*

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

FULL PRESCRIBING INFORMATION

1 INDICATIONS & USAGE

Adapalene Gel, 0.3% is indicated for the topical treatment of acne vulgaris in patients 12 years of age and older.

2 DOSAGE & ADMINISTRATION

Apply a thin film of adapalene gel, 0.3% to the entire face and any other affected areas of the skin once daily in the evening, after washing gently with a non-medicated soap. Avoid application to the areas of skin around eyes, lips, and mucous membranes. A mild transitory sensation of warmth or slight stinging may occur shortly after the application of adapalene gel, 0.3%. Patients should be instructed to minimize sun exposure. Patients may be instructed to use moisturizers for relief of dry skin or irritation.

If therapeutic results are not noticed after 12 weeks of treatment, therapy should be re-evaluated.

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

3 DOSAGE FORMS & STRENGTHS

Each gram of Adapalene Gel USP, 0.3% contains 3 mg adapalene in an off-white aqueous gel.

4 CONTRAINDICATIONS

Adapalene gel, 0.3% should not be administered to individuals who are hypersensitive to adapalene or any of the components in the gel vehicle.

5 WARNINGS AND PRECAUTIONS

5.1 Ultraviolet Light and Environmental Exposure

Exposure to sunlight, including sunlamps, should be minimized during use of adapalene gel, 0.3%. 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 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 adapalene gel, 0.3%.

5.2 Local Cutaneous Reactions

Certain cutaneous signs and symptoms of treatment such as erythema, scaling, dryness, and stinging/burning were reported with use of adapalene gel, 0.3%. These were most likely to occur during the first four weeks of treatment, were mostly mild to moderate in intensity, and usually lessened with continued use of the medication. Depending upon the severity of these side effects, patients should be instructed to either use a moisturizer, reduce the frequency of application of adapalene gel, 0.3% or discontinue use.

Avoid contact with the eyes, lips, angles of the nose, and mucous membranes. The product should not be applied to cuts, abrasions, eczematous or sunburned skin. As with other retinoids, use of "waxing" as a depilatory method should be avoided on skin treated with adapalene.

As adapalene gel has the potential to induce local irritation in some patients, concomitant use of other potentially irritating topical products (medicated or abrasive soaps and cleansers, soaps and cosmetics that have a strong drying effect and products with high concentrations of alcohol, astringents, spices, or lime) should be approached with caution.

5.3 Allergic/ Hypersensitivity Reactions

Reactions characterized by symptoms such as pruritus, face edema, eyelid edema, and lip swelling, requiring medical treatment have been reported during postmarketing use of adapalene. A patient should stop using adapalene gel, 0.3% and consult a doctor if experiencing allergic or anaphylactoid/anaphylactic reactions (e.g., skin rash, pruritus, hives, chest pain, edema, and shortness of breath) during treatment.

6 ADVERSE REACTIONS

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reactions 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 the multi-center, controlled clinical trial, signs and symptoms of local cutaneous irritation were monitored in 258 acne patients who used adapalene gel, 0.3% once daily for 12 weeks. Of the patients who experienced cutaneous irritation (erythema, scaling, dryness, and/or burning/stinging), the majority of cases were mild to moderate in severity, occurred early in treatment and decreased thereafter. The incidence of local cutaneous irritation with adapalene gel, 0.3% from the controlled clinical study is provided in the following table:

Table 1: Physician assessed local cutaneous irritation with adapalene gel

Incidence of Local Cutaneous Irritation with Adapalene Gel, 0.3% from Controlled Clinical Study (N = 253*) Maximum Severity Scores Higher Than Baseline			
	Mild	**Moderate**	**Severe**
Erythema	66 (26.1%)	33 (13.0%)	1 (0.4%)
Scaling	110 (43.5%)	47 (18.6%)	3 (1.2%)

Dryness	113 (44.7%)	43 (17.0%)	2 (0.8%)
Burning/Stinging	72 (28.5%)	36 (14.2%)	9 (3.6%)

* Total number of subjects with local cutaneous data for at least one post-Baseline evaluation.

Table 2: Patient reported local cutaneous adverse reactions with adapalene gel

	Adapalene Gel, 0.3%	**Vehicle Gel**
	N=258	**N=134**
Related* Adverse Reactions	57 (22.1%)	6 (4.5%)
Dry Skin	36 (14%)	2 (1.5%)
Skin Discomfort	15 (5.8%)	0 (0.0%)
Desquamation	4 (1.6%)	0 (0.0%)

* Selected adverse reactions defined by investigator as Possibly, Probably or Definitely Related

Related adverse reactions from the controlled clinical trial that occurred in greater than 1% of patients who used adapalene gel, 0.3% once daily included: dry skin (14.0%), skin discomfort (5.8%), pruritus (1.9%), desquamation (1.6%), and sunburn (1.2%). The following selected adverse reactions occurred in less than 1% of patients: acne flare, contact dermatitis, eyelid edema, conjunctivitis, erythema, pruritus, skin discoloration, rash, and eczema.

In a one-year, open-label safety study of 551 patients with acne who received adapalene gel, 0.3%, the pattern of adverse reactions was similar to the 12-week controlled study.

6.2 PostMarketing Experience

The following adverse reactions have been identified during post approval use of adapalene: skin irritation, application site pain, face edema, eyelid edema, lip swelling, and angioedema. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate the frequency or establish a causal relationship to drug exposure.

7 DRUG INTERACTIONS

7.1 Concomitant Topical Medications

As adapalene gel, 0.3% has the potential to induce local irritation in some patients, concomitant use of other potentially irritating topical products (medicated or abrasive soaps and cleansers, soaps and cosmetics that have a strong drying effect, and products with high concentrations of alcohol, astringents, spices, or lime) should be approached with caution. Particular caution should be exercised in using preparations containing sulfur, resorcinol, or salicylic acid in combination with adapalene gel, 0.3%. If these preparations have been used, it is advisable not to start therapy with adapalene gel, 0.3%, until the effects of such preparations have subsided.

No formal drug-drug interaction studies were conducted with adapalene gel, 0.3%.

8 USE IN SPECIFIC POPULATIONS

8.1 PREGNANCY

Teratogenic effects. Pregnancy Category C.

Retinoids may cause fetal harm, when administered to pregnant women. Adapalene has been shown to be teratogenic in rats and rabbits when administered orally (see Animal Data below). There are no adequate and well-controlled studies in pregnant women. Adapalene gel, 0.3% should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. The safety and efficacy of

adapalene gel, 0.3% in pregnancy has not been established.

Human Data

In clinical trials involving adapalene gel, 0.3% in the treatment of acne vulgaris, women of child-bearing potential initiated treatment only after having had a negative pregnancy test and used effective birth control measures during therapy. However, 6 women treated with adapalene gel, 0.3% became pregnant. One patient elected to terminate the pregnancy, two patients delivered healthy babies by normal delivery, two patients delivered prematurely and the babies remained in intensive care until reaching a healthy state and one patient was lost to follow-up.

Animal Data

- No teratogenic effects were seen in rats at oral doses of 0.15 to 5.0 mg/kg/day adapalene representing up to 6 times the maximum recommended human dose (MRHD) based on mg/m^2 comparisons. Adapalene has been shown to be teratogenic in rats and rabbits when administered orally at doses ≥ 25 mg/kg representing 32 and 65 times, respectively, the MRHD based on mg/m^2 comparisons. Findings included cleft palate, microphthalmia, encephalocele and skeletal abnormalities in the rat and umbilical hernia, exophthalmos and kidney and skeletal abnormalities in the rabbit.
- Cutaneous teratology studies in rats and rabbits at doses of 0.6, 2.0, and 6.0 mg/kg/day exhibited no fetotoxicity and only minimal increases in supernumerary ribs in both species and delayed ossification in rabbits. Systemic exposure (AUC_{0-24h}) to adapalene 0.3% gel at topical doses of 6.0 mg/kg/day in rats and rabbits represented 5.7 and 28.7 times, respectively, the exposure in acne patients treated with adapalene 0.3% gel applied to the face, chest and back (2 grams applied to 1000 cm^2 of acne involved skin).

8.3 NURSING MOTHERS

It is not known whether adapalene is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when adapalene gel, 0.3% is administered to a nursing woman.

8.4 PEDIATRIC USE

Safety and effectiveness have not been established in pediatric patients below the age of 12.

8.5 GERIATRIC USE

Clinical studies of adapalene gel, 0.3% did not include subjects 65 years of age and older to determine whether they respond differently than younger subjects. Safety and effectiveness in geriatric patients age 65 and above have not been established.

10 OVERDOSAGE

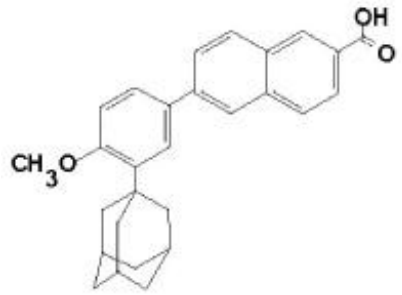
Adapalene gel, 0.3% is intended for topical use only. If the medication is applied excessively, no more rapid or better results will be obtained and marked redness, scaling, or skin discomfort may occur. Chronic ingestion of the drug may lead to the same side effects as those associated with excessive oral intake of vitamin A.

11 DESCRIPTION

Adapalene Gel USP, 0.3% contains adapalene 0.3% (3 mg/g) in a topical aqueous gel for use in the treatment of acne vulgaris, consisting of carbomer 980, edetate disodium, methylparaben, poloxamer 182, propylene glycol, purified water, and sodium hydroxide. May contain hydrochloric acid for pH adjustment.

The chemical name of adapalene is 6-[3-(1-adamantyl)-4-methoxyphenyl]-2-naphthoic acid. It is a white to off-white powder, which is soluble in tetrahydrofuran, very slightly soluble in ethanol, and

practically insoluble in water. The molecular formula is $C_{28}H_{28}O_3$ and molecular weight is 412.53. Adapalene is represented by the following structural formula.



12 CLINICAL PHARMACOLOGY

12.1 MECHANISM OF ACTION

Adapalene binds to specific retinoic acid nuclear receptors but does not bind to cytosolic receptor protein. Biochemical and pharmacological profile studies have demonstrated that adapalene is a modulator of cellular differentiation, keratinization, and inflammatory processes. However, the significance of these findings with regard to the mechanism of action of adapalene for the treatment of acne is unknown.

12.2 PHARMACODYNAMICS

Clinical pharmacodynamic studies have not been conducted for adapalene gel, 0.3%.

12.3 PHARMACOKINETICS

Systemic exposure of adapalene following topical application of adapalene gel was evaluated in a clinical study. Sixteen acne patients were treated once daily for 10 days with 2 grams of adapalene gel, 0.3% applied to the face, chest and back, corresponding to approximately 2 mg/cm^2. Fifteen patients had quantifiable (LOQ = 0.1 ng/mL) adapalene levels resulting in a mean C_{max} of 0.553 ± 0.466 ng/mL on Day 10 of treatment. The mean $AUC_{0\text{-}24hr}$ was 8.37 ± 8.46 ng.h/mL as determined in 15 of the 16 patients on Day 10. The terminal apparent half-life, determined in 15 of 16 patients, ranged from 7 to 51 hours, with a mean of 17.2 ± 10.2 hours. Adapalene was rapidly cleared from plasma and was not detected 72 hours after the last application for all but one subject. Exposure of potential circulating metabolites of adapalene was not measured. Excretion of adapalene appears to be primarily by the biliary route.

In another clinical study in patients with moderate to moderately severe acne, adapalene gel, 0.3% or adapalene gel, 0.1% was applied to the face and optionally to the trunk, once daily for 12 weeks. Seventy-eight (78) patients had plasma adapalene levels evaluated at Weeks 2, 8, and 12. Of the 209 plasma samples analyzed, adapalene concentrations were below the limit of detection (LOD = 0.15 ng/mL) of the method in all samples but three. For the three samples, traces of adapalene below the limit of quantification (LOQ = 0.25 ng/mL) of the method were found. One of these samples was taken at Week 12 from a male patient treated with adapalene gel, 0.3% who treated the face and the trunk for eight weeks (thereafter, only the face was treated). The second and third samples were from the Week 2 and 12 visits of a female patient treated with adapalene gel, 0.1% who treated only the face for 12 weeks. In this study, the average daily usage of product was 1 g/day.

13 NONCLINICAL TOXICOLOGY

13.1 CARCINOGENESIS & MUTAGENESIS & IMPAIRMENT OF FERTILITY

Carcinogenicity studies with adapalene have been conducted in mice at topical doses of 0.4, 1.3, and 4.0 mg/kg/day, and in rats at oral doses of 0.15, 0.5, and 1.5 mg/kg/day. These doses are up to 3 times (mice) and 2 times (rats) in terms of mg/m²/day the potential exposure at the maximum recommended human dose (MRHD), assumed to be 2.5 grams adapalene gel, 0.3%. In the oral study, increased incidence of benign and malignant pheochromocytomas in the adrenal medullas of male rats was observed.

No photocarcinogenicity studies were conducted. Animal studies have shown an increased risk of skin neoplasms with the use of pharmacologically similar drugs (e.g., retinoids) when exposed to UV irradiation in the laboratory or to sunlight. Although the significance of these studies to human use is not clear, patients should be advised to avoid or minimize exposure to either sunlight or artificial UV irradiation sources.

Adapalene did not exhibit mutagenic or genotoxic effects *in vitro* (Ames test, Chinese hamster ovary cell assay, mouse lymphoma TK assay) and *in vivo* (mouse micronucleus test).

Reproductive function and fertility studies were conducted in rats administered oral doses of adapalene in amounts up to 20 mg/kg/day (up to 26 times the MRHD based on mg/m² comparisons). No effects of adapalene were found on the reproductive performance or fertility of the F_0 males or females. There were also no detectable effects on the growth, development and subsequent reproductive function of the F_1 offspring.

14 CLINICAL STUDIES

The safety and efficacy of once daily use of adapalene gel, 0.3% for treatment of acne vulgaris were assessed in one 12 week, multi-center, controlled, clinical study, conducted in a total of 653 patients 12 to 52 years of age with acne vulgaris of mild to moderate severity. All female patients of child-bearing potential enrolled in the study were required to have a negative urine pregnancy test at the beginning of the study and were required to practice a highly effective method of contraception during the study. Female patients who were pregnant, nursing or planning to become pregnant were excluded from the study.

Patients enrolled in the study were Caucasian (72%), Hispanic (12%), African-American (10%), Asian (3%), and other (2%). An equal number of males (49.5%) and females (50.5%) enrolled. Success was defined as “Clear” or “Almost Clear” in the Investigator’s Global Assessment (IGA). The success rate, mean reduction, and percent reduction in acne lesion counts from Baseline after 12 weeks of treatment are presented in the following table:

Table 3: Clinical study primary efficacy results at Week 12

	Adapalene Gel, 0.3%	**Adapalene Gel, 0.1%**	**Vehicle Gel**
	N=258	**N=261**	**N=134**
IGA Success Rate	53 (21%)	41 (16%)	12 (9%)
Inflammatory Lesions			
Mean Baseline Count	27.7	28.1	27.2
Mean Absolute (%) Reduction	14.4 (51.6%)	13.9 (49.7%)	11.2 (40.7%)
Non-inflammatory Lesions			
Mean Baseline Count	39.4	41.0	40.0
Mean Absolute (%) Reduction	16.3 (39.7%)	15.2 (35.2%)	10.3 (27.2%)
Total Lesions			
Mean Baseline Count	67.1	69.1	67.2
Mean Absolute (%) Reduction	30.6 (45.3%)	29.0 (41.8%)	21.4 (33.7%)

16 HOW SUPPLIED/STORAGE AND HANDLING

Adapalene Gel USP, 0.3% is supplied in the following size.
45 g tube – NDC 0781-7142-19
45 g pump - NDC 0781-7142-70

Storage: Store at 20° – 25ºC (68º – 77ºF); excursions permitted to 15º – 30ºC (59º – 86ºF) [see USP Controlled Room Temperature]. Protect from freezing. Keep out of reach of children.

17 INFORMATION FOR PATIENTS

"See FDA-approved patient labeling (Patient Information)"

Information for Patients

Patients using adapalene gel, 0.3%, should receive the following information and instructions:

1. This medication is to be used only as directed by the physician.
2. Do not use more than the recommended amount and do not apply more than once daily as this will not produce faster results, but may increase irritation.
3. Apply a thin film of adapalene gel, 0.3% to the entire face and any other affected areas of the skin once daily in the evening, after washing gently with a non-medicated soap.
4. Avoid contact with the eyes, lips, angles of the nose, and mucous membranes.
5. Moisturizers may be used if necessary; however, products containing alpha hydroxy or glycolic acids should be avoided.
6. Exposure of the eye to this medication may result in reactions such as swelling, conjunctivitis, and eye irritation.
7. This medication should not be applied to cuts, abrasions, eczematous, or sunburned skin.
8. Wax depilation should not be performed on treated skin due to the potential for skin erosions.
9. Minimize exposure to sunlight including sunlamps. Recommend the use of sunscreen products and protective apparel (e.g., hat) when exposure cannot be avoided.
10. During the early weeks of therapy, an apparent exacerbation of acne may occur. This may be due to the action of the medication on previously unseen lesions and should not be considered a reason to discontinue therapy.
11. Contact the doctor if skin rash, pruritus, hives, chest pain, edema, and shortness of breath occurs, as these may be signs of allergy or hypersensitivity.
12. It is for external use only.

Manufactured by
TOLMAR Inc.
Fort Collins, CO 80526 for
Sandoz Inc.
Princeton, NJ 08540

44457 Rev. 3 07/16

SPL PATIENT PACKAGE INSERT

Patient Information
Adapalene Gel, 0.3%
(a dap' a leen)

Important: For use on the skin only (topical). Do not use Adapalene Gel, 0.3% in or on your mouth, eyes, or vagina.

Read this Patient Information that comes with Adapalene Gel, 0.3% 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 treatment or your medical condition. If you have any questions about Adapalene Gel, 0.3%, talk with your doctor or pharmacist.

What is Adapalene Gel, 0.3%?

Adapalene Gel, 0.3% is a prescription medicine for skin use only (topical) used to treat acne vulgaris in people 12 years of age and older.

Acne vulgaris is a condition in which the skin has blackheads, whiteheads and pimples.

It is not known if Adapalene Gel, 0.3% is safe and effective in children younger than 12 years of age or in people 65 years of age and older.

Who should not use Adapalene Gel, 0.3%?

Do not use Adapalene Gel, 0.3% if you:

● are allergic to adapalene or any of the ingredients in Adapalene Gel, 0.3%. See the end of this Patient Information for a complete list of ingredients in Adapalene Gel.

What should I tell my doctor before using Adapalene Gel, 0.3%?

Before you use Adapalene Gel, 0.3%, tell your doctor if you:

- have other skin problems, including cuts or sunburn
- have any other medical conditions
- are pregnant or planning to become pregnant. It is not known if Adapalene Gel, 0.3% can harm your unborn baby. Talk to your doctor if you are pregnant or plan to become pregnant.
- are breastfeeding or plan to breastfeed. It is not known if Adapalene Gel, 0.3% passes into your breast milk and if it can harm your baby. Talk to your doctor about the best way to feed your baby if you use Adapalene Gel, 0.3%.

Tell your doctor about all the medicines you take, including prescription and nonprescription medicines, vitamins and herbal supplements.

Especially tell your doctor if you use any other medicine for acne. Using Adapalene Gel, 0.3% with topical medicines that contain sulfur, resorcinol or salicylic acid may cause skin irritation.

Know the medicines you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine.

How should I use Adapalene Gel, 0.3%?

- Use Adapalene Gel, 0.3% exactly as your doctor tells you to use it. Adapalene Gel, 0.3% is for skin use only. Do not use Adapalene Gel, 0.3% in or on your mouth, eyes, or vagina.
- Apply Adapalene Gel, 0.3% 1 time a day. Do not use more Adapalene Gel, 0.3% than you need to cover the treatment area. Using too much Adapalene Gel, 0.3% or using it more than 1 time a day may increase your chance of skin irritation.

Applying Adapalene Gel, 0.3%:

- Wash the area where Adapalene Gel, 0.3% will be applied with a soap that does not contain a medicine and pat dry.
- Adapalene Gel, 0.3% comes in a tube and a pump. If you have been prescribed the:
  • Tube: Squeeze a small amount onto your fingertips and spread a thin layer over the entire face and any other affected areas.
  • Pump: Depress the pump to dispense a small amount of Adapalene Gel, 0.3% and spread a thin layer over the entire face and any other affected areas.

What should I avoid while using Adapalene Gel, 0.3%?

- You should avoid spending time in sunlight or artificial sunlight, such as tanning beds or sunlamps. Adapalene Gel, 0.3% can make your skin sensitive to sun and the light from tanning beds and

sunlamps. You should wear sunscreen and wear a hat and clothes that cover the areas treated with Adapalene Gel, 0.3% if you have to be in sunlight.
- You should avoid weather extremes such as wind and cold as this may cause irritation to your skin.
- You should avoid applying Adapalene Gel, 0.3% to cuts, abrasions and sunburned skin.
- You should avoid skin products that may dry or irritate your skin such as harsh soaps, astringents, cosmetics that have strong skin drying effects and products containing high levels of alcohol.
- You should avoid the use of "waxing" as a hair removal method on skin treated with Adapalene Gel, 0.3%.

What are the possible side effects of Adapalene Gel, 0.3%?

Adapalene Gel, 0.3% may cause serious side effects including:
- **Local skin reactions.** Local skin reactions are most likely to happen during the first 4 weeks of treatment and usually lessen with continued use of Adapalene Gel, 0.3%. Signs and symptoms of local skin reaction include:
  - Redness
  - Dryness
  - Scaling
  - Stinging or burning
- **Allergic reactions**. Adapalene Gel, 0.3% may cause an allergic reaction that may require medical treatment. Stop using Adapalene Gel, 0.3% and tell your doctor right away if you have any of these symptoms of an allergic reaction:
  - skin rash, itching or hives
  - trouble breathing or chest pain
  - swelling of your face, eyes, lips, tongue or throat

You may use a moisturizer for relief of dry skin or irritation, however you should avoid products that contain alpha hydroxy or glycolic acid.

The most common side effects of Adapalene Gel, 0.3% are:
- skin pain
- skin peeling
- sunburn

Tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of Adapalene Gel, 0.3%. For more information, ask your doctor or pharmacist.

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

You may also report side effects to Sandoz Inc. at 1-800-525-8747.

How should I store Adapalene Gel, 0.3%?
- Store Adapalene Gel, 0.3% at room temperature between 68°F to 77°F (20° C to 25°C).
- Do not freeze Adapalene Gel, 0.3%.

Keep Adapalene Gel, 0.3% and all medicines out of the reach of children.

General information about Adapalene Gel, 0.3%

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information Leaflet. Do not use Adapalene Gel, 0.3% for a condition for which it was not prescribed. Do not give Adapalene Gel, 0.3% to other people, even if they have the same symptoms you have. It may harm them.

This Patient Information leaflet summarizes the most important information about Adapalene Gel, 0.3%.

If you would like more information, talk with your doctor. You can also ask your doctor or pharmacist for information about Adapalene Gel, 0.3% that is written for health professionals.

What are the ingredients in Adapalene Gel, 0.3%?

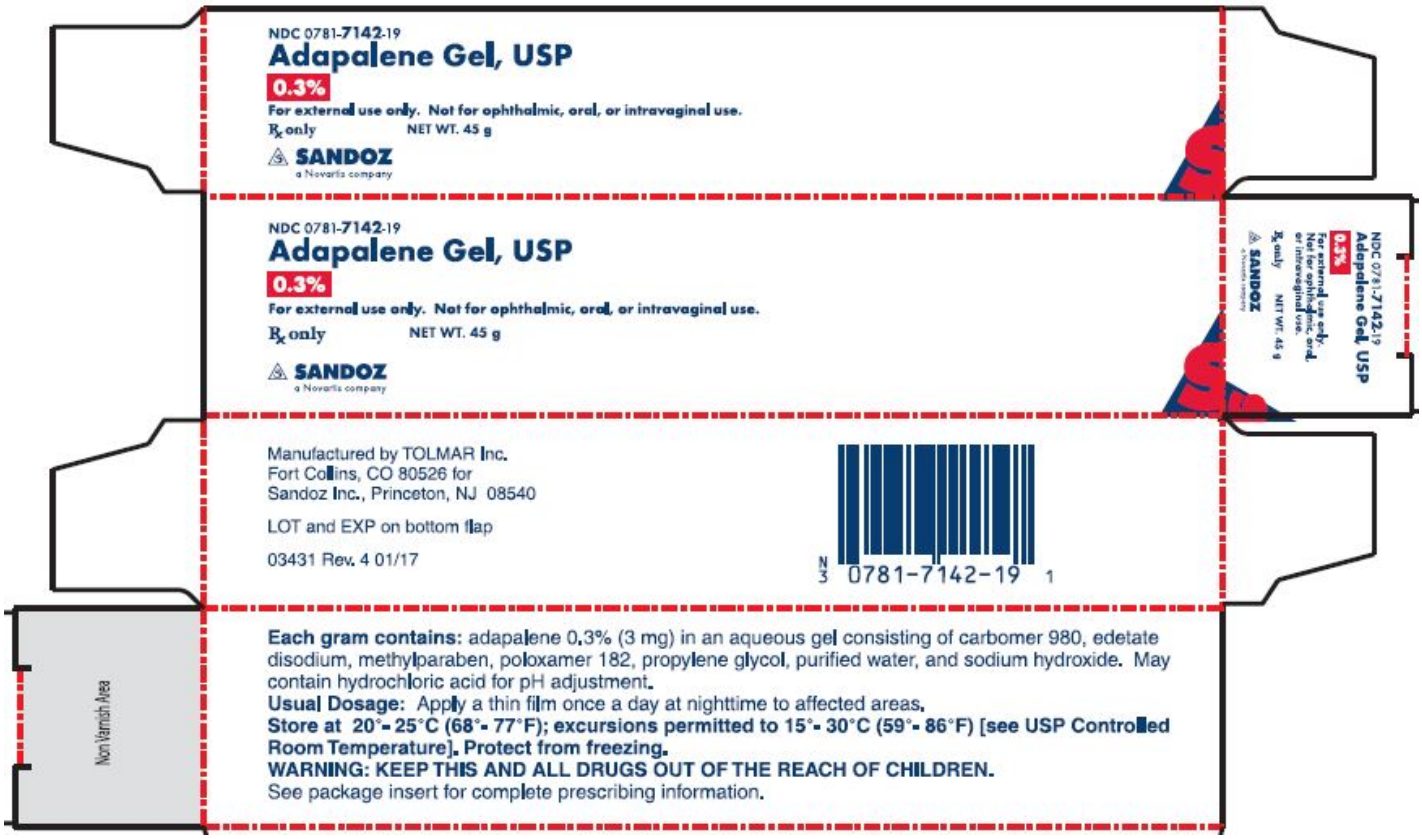
Active ingredient: adapalene

Inactive ingredients: carbomer 980, edetate disodium, methylparaben, poloxamer 182, propylene glycol, purified water and sodium hydroxide. May contain hydrochloric acid for pH adjustment.

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

Manufactured by TOLMAR Inc.
Fort Collins, CO 80526 for
Sandoz Inc.
Princeton, NJ 08540
44457 Rev. 3 07/16

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



ADAPALENE

adapalene gel

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0781-7142
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ADAPALENE (UNII: 1L4806J2QF) (ADAPALENE - UNII:1L4806J2QF)	ADAPALENE	3 mg in 1 g

Inactive Ingredients	
Ingredient Name	Strength
CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLOXAMER 182 (UNII: JX0HIX6OAG)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0781-7142-70	1 in 1 BOTTLE, PUMP	04/28/2014	
1		45 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		
2	NDC:0781-7142-19	1 in 1 CARTON	04/28/2014	
2		45 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA200298	04/28/2014	

Labeler - Sandoz Inc. (005387188)

Establishment

Name	Address	ID/FEI	Business Operations
TOLMAR Inc.		791156578	ANALYSIS(0781-7142) , LABEL(0781-7142) , MANUFACTURE(0781-7142) , PACK(0781-7142)

Revised: 10/2019 Sandoz Inc.