ADAPALENE- adapalene gel
Alembic Pharmaceuticals Limited

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.

ADAPALENE gel, for topical use
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

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

DOSAGE FORMS AND STRENGTHS

Gel, 0.3% (3)

CONTRAINDICATIONS

Contraindicated in patients who have known hypersensitivity to adapalene or any excipient of adapalene gel. (4)

WARNINGS AND PRECAUTIONS

- *Allergic/ Hypersensitivity Reactions:*Allergy/hypersensitivity reactions include anaphylaxis angioedema, face edema, eyelid edema, lip swelling, and pruritis. Discontinue adapalene gel in the event of an allergic/hypersensitivity reaction. (5.1)
- *Ultraviolet Light and Environmental Exposure:*Avoid exposure to sunlight and sunlamps. Wear sunscreen when sun exposure cannot be avoided (5.2).
- *Local Cutaneous Reactions:*Erythema, scaling, dryness, and stinging/burning were reported with use of adapalene gel. 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).

ADVERSE REACTIONS

The most frequently reported (≥1%) adverse reactions were erythema, scaling, dryness, and/or burning/stinging. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch.*
See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.
Revised: 3/2025

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FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

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

2 DOSAGE AND ADMINISTRATION

Wash affected areas gently with a non-medicated soap. Apply a thin film of adapalene gel to the entire face and any other affected areas of the skin once daily in the evening. 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.

Instruct patients to minimize sun exposure and 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 AND STRENGTHS

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

4 CONTRAINDICATIONS

Adapalene gel is contraindicated in patients who have known hypersensitivity to adapalene or any excipient of adapalene gel *[see WARNINGS AND PRECAUTIONS (5.1)].*

5 WARNINGS AND PRECAUTIONS

5.1 Allergic/ Hypersensitivity Reactions

Adverse reactions including anaphylaxis angioedema, face edema, eyelid edema, lip swelling, and pruritus that sometimes required medical treatment have been reported during postmarketing use of adapalene. Advise a patient to stop using adapalene gel and seek medical attention if experiencing allergic or anaphylactoid/anaphylactic reactions during treatment.

5.2 Ultraviolet Light and Environmental Exposure

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

5.3 Local Cutaneous Reactions

Cutaneous signs and symptoms such as erythema, scaling, dryness, and stinging/burning were reported with use of adapalene gel. 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 or discontinue use.

Avoid application 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.

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 subjects who used adapalene gel once daily for 12 weeks. Of the subjects 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 from the controlled clinical trial is provided in the following table:

Table 1: Physician assessed local cutaneous irritation with Adapalene Gel

Incidence of Local Cutaneous Irritation with Adapalene Gel (N = 253*) Maximum Severity Scores Higher Than			
	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	**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

The following adverse reactions occurred in less than 1% of subjects: acne flare, contact dermatitis, eyelid edema, conjunctivitis, erythema, pruritus, skin discoloration, rash, and eczema.

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

6.2 Post-Marketing Experience

The following adverse reactions have been identified during post approval use of adapalene:

Immune system disorders: angioedema, face edema, lip swelling

Skin disorders: application site pain

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.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Available data from clinical trials with adapalene gel use in pregnant women are insufficient to establish a drug-associated risk of major birth defects, miscarriage or other adverse maternal or fetal outcomes. In animal reproduction studies, oral administration of adapalene to pregnant rats and rabbits during organogenesis at dose exposures 40 and 81 times, respectively, the human exposure at the maximum recommended human dose (MRHD) of 2 g resulted in fetal skeletal and visceral malformations *(see Data)*.

The background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defects, loss, or other adverse outcomes. In the U.S. general population the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies are 2 to 4% and 15 to 20%, respectively.

Data

Animal Data

No malformations were observed in rats treated with oral adapalene doses of 0.15 to 5.0 mg/kg/day, up to 8 times the MRHD based on a mg/m^{2}comparison. However, malformations were observed in rats and rabbits when treated with oral doses of ≥ 25 mg/kg/day adapalene (40 and 81 times the MRHD, respectively, based on a mg/m^{2}comparison). Findings included cleft palate, microphthalmia, encephalocele, and skeletal abnormalities in rats and umbilical hernia, exophthalmos, and kidney and skeletal abnormalities in rabbits.

Dermal adapalene embryofetal development studies in rats and rabbits at doses up to 6.0 mg/kg/day (9.7 and 19.5 times the MRHD, respectively, based on a mg/m^{2}comparison) exhibited no fetotoxicity and only minimal increases in skeletal variations (supernumerary ribs in both species and delayed ossification in rabbits).

8.2 Lactation

Risk Summary

There are no data on the presence of topical adapalene gel or its metabolite in human milk, the effects on the breastfed infant, or the effects on milk production. In animal studies, adapalene is present in rat milk with oral administration of the drug. When a drug is present in animal milk, it is likely that the drug will be present in human milk. It is possible that topical administration of large amounts of adapalene could result in sufficient systemic absorption to produce detectable quantities in human milk *(see*

Clinical Considerations). The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for adapalene gel and any potential adverse effects on the breastfed child from adapalene gel, or from the underlying maternal condition.

Clinical Considerations

To minimize potential exposure to the breastfed infant via breastmilk, use adapalene gel on the smallest area of skin and for the shortest duration possible while breastfeeding. Avoid application of adapalene gel to areas with increased risk for potential ingestion by or ocular exposure to the breastfeeding child.

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 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.

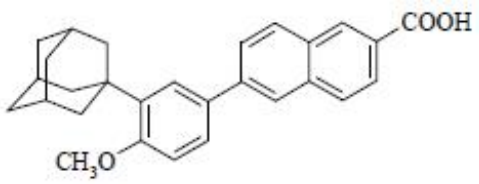
10 OVERDOSAGE

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 USP, 0.3% (3 mg/g) in a topical aqueous gel for use in the treatment of acne vulgaris, consisting of carbopol 980, edetate disodium, methylparaben, poloxamer 124, propylene glycol, purified water, and sodium hydroxide. May contain hydrochloric acid for pH adjustment.

The chemical name of adapalene, USP 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, USP 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.

12.3 Pharmacokinetics

Systemic exposure of adapalene following topical application of adapalene gel was evaluated in a clinical trial. Sixteen acne subjects were treated once daily for 10 days with 2 grams of adapalene gel applied to the face, chest and back, corresponding to approximately 2 mg/cm^2. Fifteen subjects 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 subjects on Day 10. The terminal apparent half-life, determined in 15 of 16 subjects, 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 trial in subjects 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) subjects 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 subject 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 Week2 and 12 visits of a female subject 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

No carcinogenicity, genotoxicity, or impairment of fertility studies were conducted with adapalene gel.

Carcinogenicity studies with adapalene were conducted in mice at topical doses of 0.4, 1.3, and 4.0 mg/kg/day (1.2, 3.9, and 12 mg/m^2/day) and in rats at oral doses of 0.15, 0.5, and 1.5 mg/kg/day (0.9, 3.0, and 9.0 mg/m^2/day). The highest dose levels are 3.2 (mice) and 2.4 (rats) times the MRHD based on a mg/m^2 comparison. In the rat study, an increased incidence of benign and malignant pheochromocytomas reported in the adrenal medulla of male rats was observed.

Adapalene was not mutagenic or genotoxic *in vitro* (Ames test, Chinese hamster ovary

cell assay, or mouse lymphoma TK assay) or *in vivo* (mouse micronucleus test).

In rat oral studies, 20 mg/kg/day adapalene (32 times the MRHD based on a mg/m^2 comparison) did not affect the reproductive performance and fertility of F_0 males and females or the growth, development, or reproductive function of F_1 offspring.

14 CLINICAL STUDIES

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

Subjects enrolled in the trial 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 Mean Absolute (%) Reduction	 27.7 14.4 (51.6%)	 28.1 13.9 (49.7%)	 27.2 11.2 (40.7%)
Non-inflammatory Lesions Mean Baseline Count Mean Absolute (%) Reduction	 39.4 16.3 (39.7%)	 41.0 15.2 (35.2%)	 40.0 10.3 (27.2%)
Total Lesions Mean Baseline Count Mean Absolute (%) Reduction	 67.1 30.6 (45.3%)	 69.1 29.0 (41.8%)	 67.2 21.4 (33.7%)

16 HOW SUPPLIED/STORAGE AND HANDLING

Adapalene gel USP, 0.3% is supplied in the following size.

15 g tube – NDC 46708-549-15

45 g tube – NDC 46708-549-45

45 g pump – NDC 46708-549-46

Storage*:* Store at controlled room temperature 68° to 77°F (20° to 25°C) with excursions permitted between 59° to 86°F (15° to 30°C) [See USP Controlled Room

Temperature]. 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)

Information for Patients

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

1. Apply a thin film of adapalene gel to the entire face and any other affected areas of the skin once daily in the evening. Apply a thin film of adapalene gel 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. Avoid contact with the eyes, lips, angles of the nose, and mucous membranes
3. Moisturizers may be used if necessary; however, products containing alpha hydroxy or glycolic acids should be avoided.
4. This medication should not be applied to cuts, abrasions, eczematous, or sunburned skin.
5. Wax depilation should not be performed on treated skin due to the potential for skin erosions.
6. Minimize exposure to sunlight including sunlamps. Recommend the use of sunscreen products and protective apparel (e.g., hat) when exposure cannot be avoided.
7. 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.
8. This product is for external use only.
9. Lactation: Use adapalene gel on the smallest area of skin and for the shortest duration possible while breastfeeding. Avoid application of adapalene gel to areas with increased risk for potential ingestion by or ocular exposure to the breastfeeding child. *[*See *Use in Specific Populations, Lactation (8.2)]*

Manufactured by:

Alembic Pharmaceuticals Limited

(Derma Division),

Karakhadi, Vadodara 391450, India.

Mfg. License No.: G/25/2216

Revised: 03/2025

PATIENT INFORMATION **Adapalene (a dap' a leen)** **Gel, 0.3%**
Important: Adapalene gel is for use on the skin only (topical). Do not use adapalene gel in or on your mouth, eyes, or vagina.
What is adapalene gel? Adapalene gel is a prescription medicine used on the skin (topical) to treat acne vulgaris in people 12 years of age and older. It is not known if adapalene gel is safe and effective in children under 12 years of age

or in people 65 years of age and older.

Do not use adapalene gel if you are allergic to adapalene or any of the ingredients in adapalene gel. See the end of this Patient Information leaflet for a complete list of ingredients in adapalene gel.

Before using adapalene gel , tell your healthcare provider about all your medical conditions, including if you:

- have other skin problems, including cuts, abrasions, sunburn, or skin that is dry, itchy, or red.
- are pregnant or plan to become pregnant. It is not known if adapalene gel, can harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if adapalene gel passes into your breast milk and if it can harm your baby. Talk to your healthcare provider about the best way to feed your baby if you use adapalene gel. If you use adapalene gel while breastfeeding, use adapalene gel on the smallest area of the skin and for the shortest time needed. Do not apply adapalene gel to areas that may increase the risk of getting adapalene gel in your child's mouth or eyes.

Tell your healthcare provider about all of the medicines you take , including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How should I use adapalene gel?

- Use adapalene gel exactly as your healthcare provider tells you to use it.
- Apply adapalene gel 1 time a day in the evening.
- Tell your healthcare provider if you do not notice a difference in your acne after using adapalene gel for 12 weeks.

Applying adapalene gel:

- Wash the area where adapalene gel will be applied with a mild soap that does not contain a medicine and pat dry.
- Adapalene gel 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 and spread a thin layer over the entire face and any other affected area.
  - **Do not** apply adapalene gel on areas of the skin around your eyes, lips, nose, and mouth.

- Wash your hands after applying adapalene gel.

What should I avoid while using adapalene gel?

- Avoid spending time in sunlight, including sunlamps. Adapalene gel can make your skin sensitive to the sun and the light from sunlamps. Use sunscreen and wear hat and clothes that cover the areas treated with adapalene gel if you have to be in sunlight.
- Cold weather and wind may irritate your skin treated with adapalene gel.
- **Do not** apply adapalene gel to cuts, abrasions, sunburned skin, or skin that is dry, itchy, or red.
- Avoid skin products that may dry or irritate your skin such as harsh soaps or cleansers, soaps and cosmetics that make your skin dry, and products that contain high levels of alcohol, astringents, spices, or limes.

- Avoid the use of "waxing" as a hair removal method on skin treated with adapalene gel.

What are the possible side effects of adapalene gel?
Adapalene gel may cause serious side effects including:

- **Allergic reactions.** Adapalene gel may cause serious allergic reactions that sometimes may require medical treatment. Stop using adapalene gel and tell your healthcare provider or get medical help right away if you have any of these symptoms of an allergic reaction:

o skin rash, itching or hives
o trouble breathing or chest pain
o swelling of your face, eyes, lips, tongue, or throat

- **Skin reactions at the treated site.** Adapalene gel may cause skin reactions including redness, scaling, dryness, stinging, and burning. These skin reactions are most likely to happen during the first 4 weeks of treatment, and usually lessen with continued use of adapalene gel. Your healthcare provider may tell you to use a moisturizer, decrease how often you use adapalene gel, or stop treatment with adapalene gel if you get any skin reactions. If you use a moisturizer, you should avoid moisturizers that contain alpha hydroxy or glycolic acid. Ask your healthcare provider or pharmacist if you are not sure.

The most common side effects of adapalene gel include dry skin, skin pain, itching, and skin peeling.
These are not all the possible side effects of adapalene gel.
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 at 1-866-210-9797.

How should I store adapalene gel?

- Store adapalene gel, 0.3% at room temperature between 68° F to 77° F (20° C to 25° C).
- **Do not** freeze adapalene gel.

Keep adapalene gel and all medicines out of the reach of children.

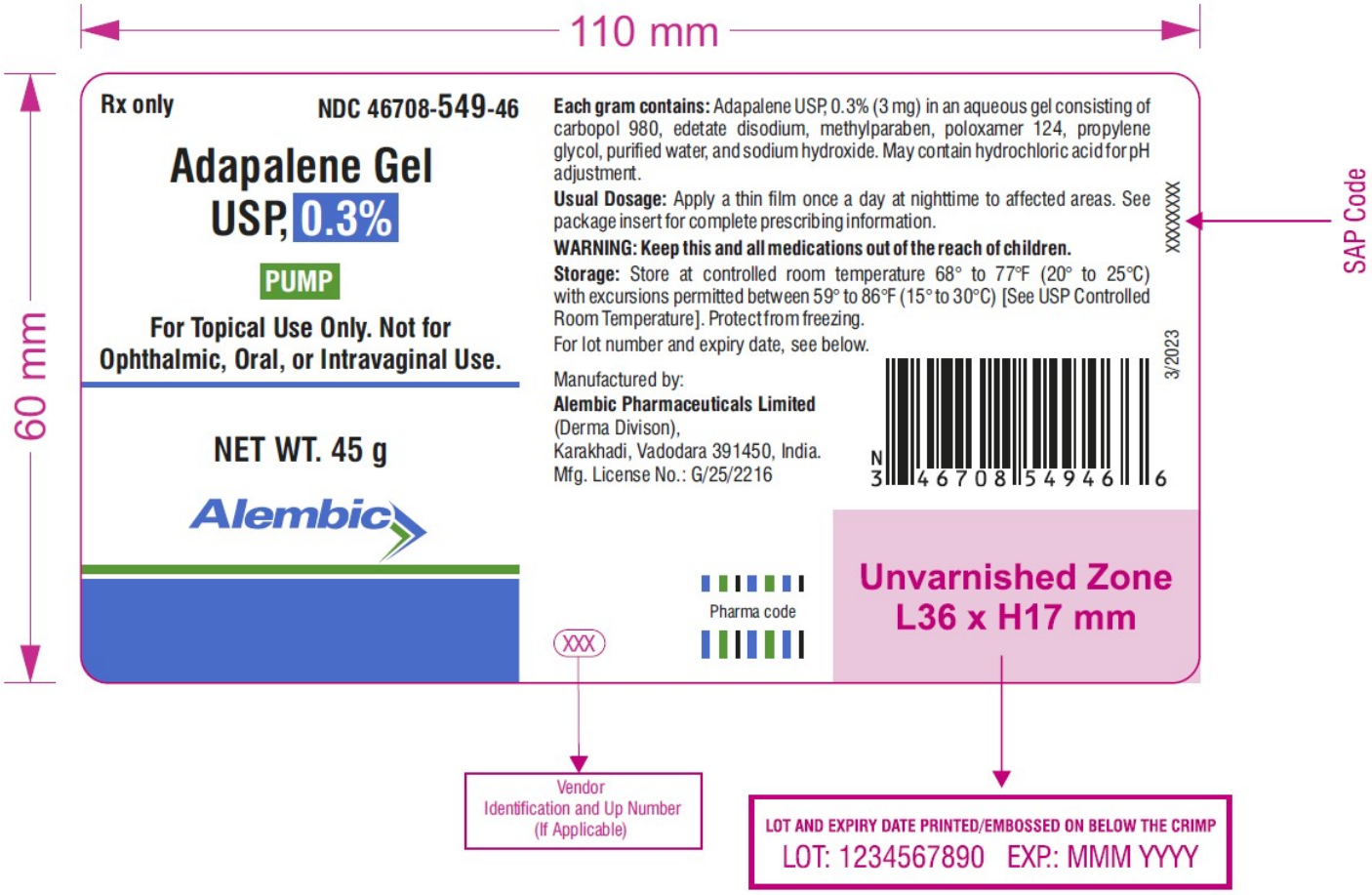
General information about the safe and effective use of adapalene gel.
Medicines are sometimes prescribed for purposes other than those listed in a Patient Information Leaflet. Do not use adapalene gel for a condition for which it was not prescribed. Do not give adapalene gel to other people, even if they have the same symptoms you have. It may harm them. You can also ask your pharmacist or healthcare provider for information about adapalene gel that is written for health professionals.

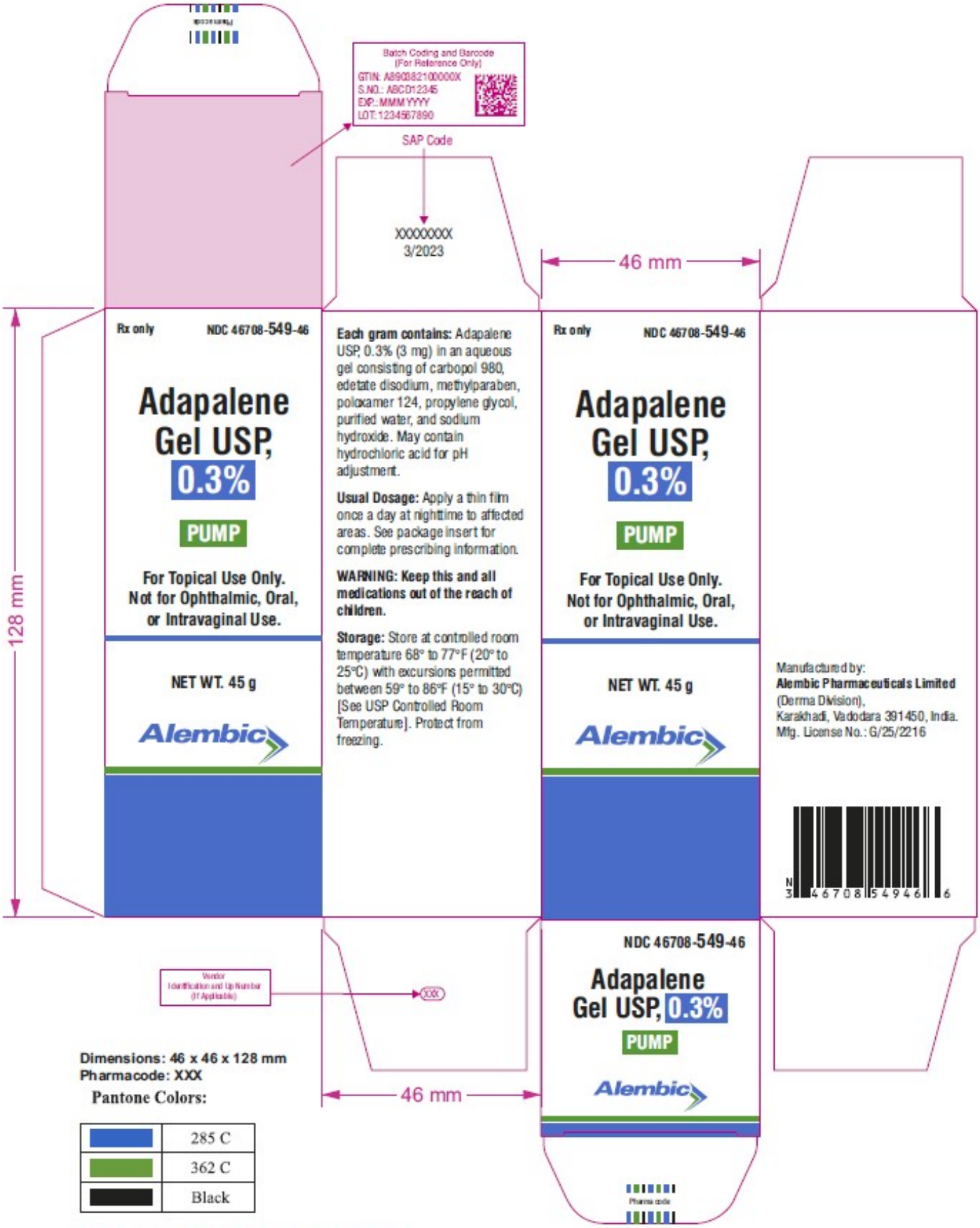
What are the ingredients in adapalene gel?
Active ingredient: adapalene
Inactive ingredients: carbopol 980, edetate disodium, methylparaben, poloxamer 124, propylene glycol, purified water, and sodium hydroxide. May contain hydrochloric acid for pH adjustment.
Manufactured by:
Alembic Pharmaceuticals Limited
(Derma Division),
Karakhadi, Vadodara 391450, India.

Mfg. License No.: G/25/2216
For more information, call at 1-866-210-9797.

This Patient Information has been approved by the U.S. Food and Drug Administration. 03/2025

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

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LOT: 1234567890
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XXXXXXX
3/2023
46 mm
128 mm
Rx only
NDC 46708-549-46
Adapalene Gel USP, 0.3%
PUMP
For Topical Use Only.
Not for Ophthalmic, Oral, or Intravaginal Use.
NET WT. 45 g
Alembic
Each gram contains: Adapalene USP, 0.3% (3 mg) in an aqueous gel consisting of carbopol 980, edetate disodium, methylparaben, poloxamer 124, propylene glycol, purified water, and sodium hydroxide. May contain hydrochloric acid for pH adjustment.
Usual Dosage: Apply a thin film once a day at nighttime to affected areas. See package insert for complete prescribing information.
WARNING: Keep this and all medications out of the reach of children.
Storage: Store at controlled room temperature 68° to 77°F (20° to 25°C) with excursions permitted between 59° to 86°F (15° to 30°C) [See USP Controlled Room Temperature]. Protect from freezing.
Manufactured by:
Alembic Pharmaceuticals Limited
(Derma Division),
Karakhadi, Vadodara 391450, India.
Mfg. License No.: G/25/2216
Vendor Identification and Up Number (If Applicable)
XXX
Dimensions: 46 x 46 x 128 mm
Pharmacode: XXX
Pantone Colors:
285 C
362 C
Black
NOTE: Key line may adjust by vendor as per auto cartonator drawing.
Pharma code

Rx only

NDC 46708-549-46

Adapalene Gel USP, 0.3%

PUMP

FOR TOPICAL USE ONLY

NET WT.45 g

Alembic

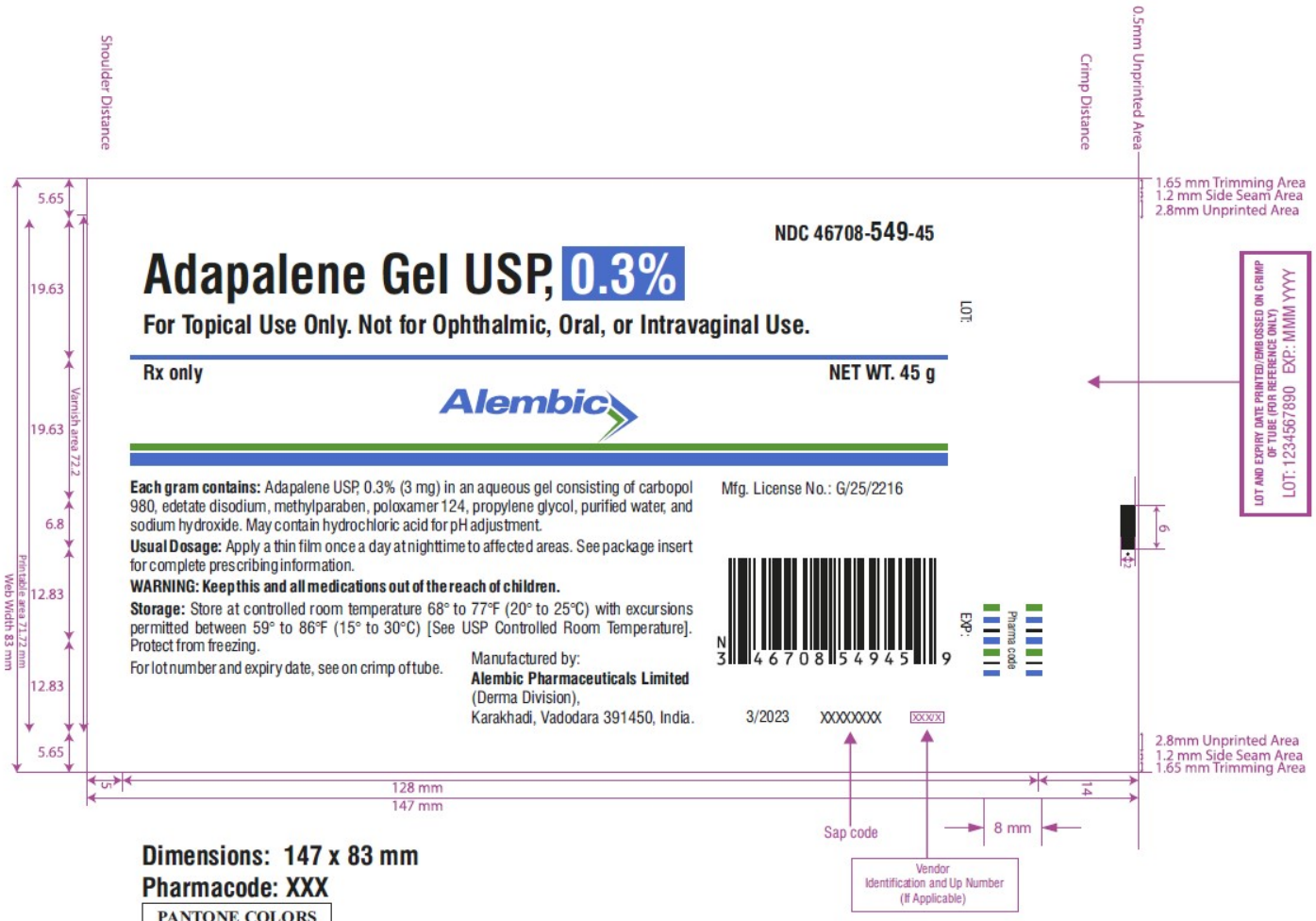
For topical use only. Not for ophthalmic, oral, or intravaginal use.

Usual dosage: apply a thin film once a day at nighttime to affected areas. See package insert for complete prescribing information.

Each gram contains: adapalene USP, 0.3% (3 mg) in an aqueous gel consisting of carbopol 980, edetate disodium, methylparaben, poloxamer 124, propylene glycol, purified water, and sodium hydroxide. May contain hydrochloric acid for pH adjustment.

Storage: Store at controlled room temperature 68° to 77°F (20° to 25°C) with excursions permitted between 59° to 86°F (15° to 30°C) [See USP Controlled Room Temperature]. Protect from freezing.

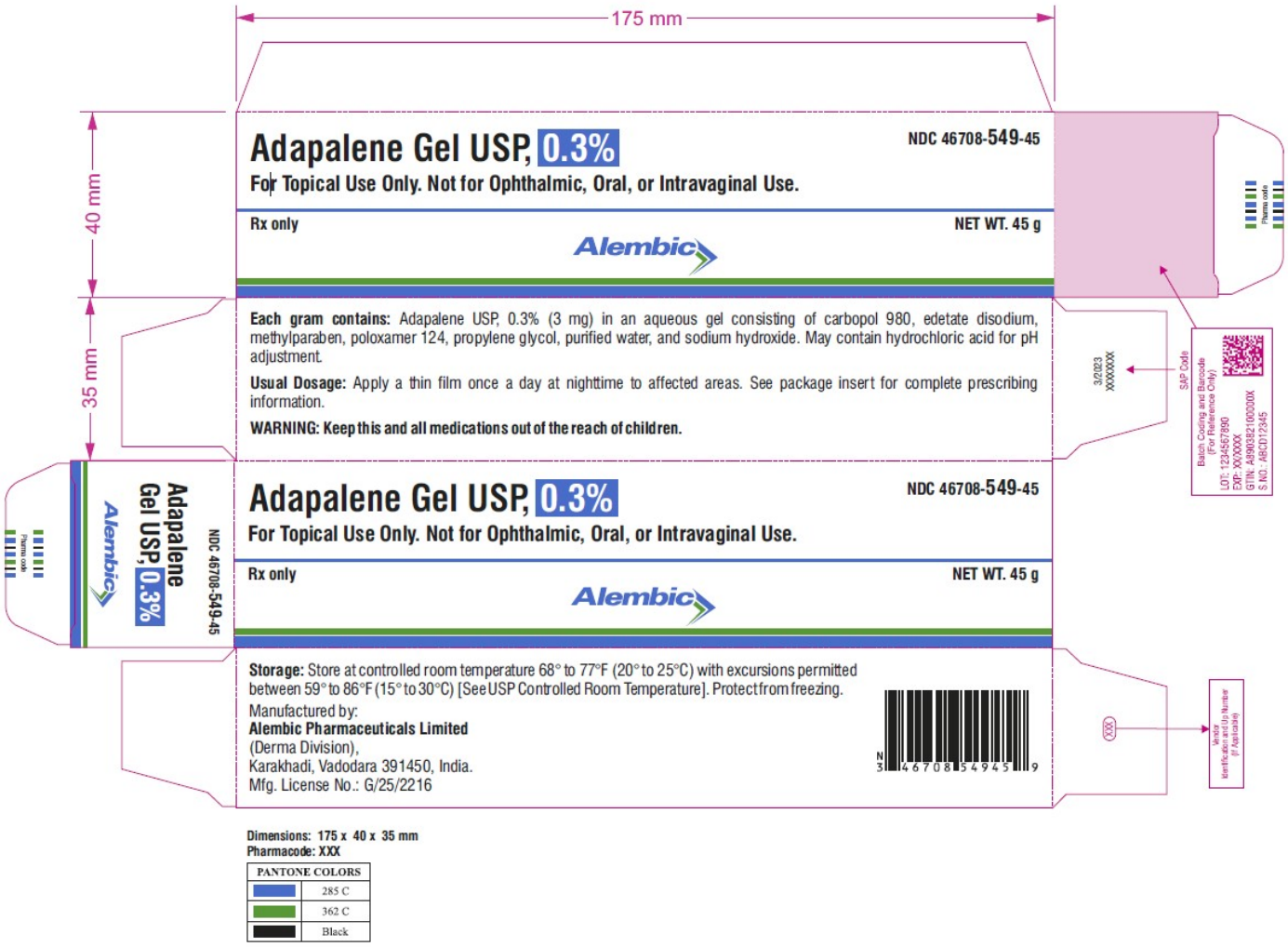
For lot number and expiration date see below the crimp of Pump.



Dimensions: 147 x 83 mm

Pharmacode: XXX

PANTONE COLORS	
	285 C
	362 C
	Black



Rx only

NDC 46708-549-45

Adapalene Gel USP, 0.3%

TUBE

FOR TOPICAL USE ONLY

NET WT.45 g

Alembic

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

Usual dosage: apply a thin film once a day at nighttime to affected areas. See package insert for complete prescribing information.

Each gram contains: adapalene USP, 0.3% (3 mg) in an aqueous gel consisting of carbopol 980, edetate disodium, methylparaben, poloxamer 124, propylene glycol, purified water, and sodium hydroxide. May contain hydrochloric acid for pH adjustment.

Storage: Store at controlled room temperature 68° to 77°F (20° to 25°C) with excursions permitted between 59° to 86°F (15° to 30°C) [See USP Controlled Room Temperature]. Protect from freezing.

For lot number and expiration date, see on crimp of tube.

ADAPALENE

adapalene gel

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:46708-549
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 124 (UNII: 1S66E28KXA)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:46708-549-15	1 in 1 CARTON	03/26/2025	
1		15 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:46708-549-45	1 in 1 CARTON	03/26/2025	
2		45 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:46708-549-46	1 in 1 CARTON	03/26/2025	
3		45 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA213508	03/26/2025	

Labeler - Alembic Pharmaceuticals Limited (650574663)

Registrant - Alembic Pharmaceuticals Limited (650574663)

Establishment

Name	Address	ID/FEI	Business Operations
Alembic Pharmaceuticals Limited		871411532	MANUFACTURE(46708-549) , ANALYSIS(46708-549)

Revised: 3/2025 Alembic Pharmaceuticals Limited