

ADAPALENE- adapalene gel
CVS PHARMACY, INC

Adapalene Gel USP 0.1 percent ENE 1.6 OZ

Active ingredient

Adapalene USP 0.1% (retinoid)*

*read consumer information leaflet

Purpose

Acne treatment

Use

- For the treatment of acne

Warnings

For external use only

Do not use

- on damaged skin (cuts, abrasions eczema, sunburn)
- if you are allergic to adapalene or any of the ingredients in this product

Pregnancy/Breastfeeding,

ask a doctor before use.

When using this product

- limit sun exposure, including light from tanning beds, and use sunscreen when going outdoors.
- do not wax to remove hair in areas where the product has been applied
- during the early weeks of use, your acne may appear to worsen before it improves (this is normal); continue using as directed, unless you get irritation that become severe
- irritation (redness, itching, dryness, burning) is more likely to occur:
 - in the first few weeks of use
 - if using more than one topical acne medication at a time
 - but irritation usually lessens with continued use of this product
- it may take up to 3 months of once daily use to see result
- avoid product contact eyes, lips, and mouth. If contact occurs immediately flush the area with water.
- wash hands after use

Stop use and ask a doctor if

- you become pregnant, or planning to become pregnant while using this product
- you have symptoms of an allergic reaction (such as itching, rash, hives, swelling of the lips, eyelids, and shortness of breath)
- irritation become severe
- you see no improvement after 3 months of once daily use

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

Adults and children 12 years of age and older:

- use **once** daily
- clean the skin gently and pat dry before applying the product
- cover the entire affected area with a thin layer. For example, if your acne is on the face, apply the product to the entire face.
- do not use more than one time a day. Applying more than directed will not provide faster or better results, but may worsen skin irritation.

Children under 12 years of age: ask a doctor

Other information

- store at room temperature 68° to 77°F
- protect from freezing

Inactive ingredients

carbomer homopolymer type C, edetate disodium, methylparaben, poloxamer 182, propylene glycol, purified water. May contain hydrochloric acid and/or sodium hydroxide to adjust sodium hydroxide pH.

Questions or comments?

Call **1-877-753-3935** Monday-Friday 9AM-5PM EST

Principal Display Panel

Compare to the active ingredient in Differin® Gel†

ADAPALENE GEL USP 0.1%

ACNE TREATMENT

- PREVIOUSLY AVAILABLE ONLY BY PRESCRIPTION
- DERMATOLOGIST DEVELOPED AND TESTED
- ONCE DAILY TOPICAL RETINOID*

OIL FREE

FRAGRANCE FREE

NET WT OZ (g)

*Read consumer information leaflet before use

*Read carton and enclosed consumer information leaflet before using this product. Keep this carton and consumer information leaflet. They contain important information.

†This product is not manufactured or distributed by Galderma Laboratories, L.P. distributor of Differin® Gel.

Distributed by:

PL Developments

200 Hicks Street,

Westbury, NY 11590

Product Label

Drug Facts

Active ingredient

Adapalene, USP 0.1% (retinoid)* Acne treatment
*read consumer information leaflet

Purpose

Use ■ For the treatment of acne

Warnings

For external use only

Do not use

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- if you are allergic to adapalene or any of the ingredients in this product

If pregnant or breast-feeding, ask a doctor before use.

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Compare to the active ingredient in Differin® Gel †

NDC 51316-114-05

ADAPALENE GEL USP 0.1%

ACNE TREATMENT

PREVIOUSLY AVAILABLE
ONLY BY PRESCRIPTION

DERMATOLOGIST DEVELOPED
AND TESTED

ONCE DAILY TOPICAL RETINOID*

OIL FREE
FRAGRANCE FREE

NET WT 0.5 OZ (15 g)

*Read consumer information leaflet before use

*Read carton and enclosed consumer information leaflet before using this product. Keep this carton and consumer information leaflet. They contain important information.

Actual Size One Tube Inside



3 59726 11406 6

PLD-8796A FC008851 Product of Italy

Lot No.:

Exp. Date:

CVS HEALTH Acne Treatment

ADAPALENE

adapalene gel

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:51316-114

Route of Administration	TOPICAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ADAPALENE (UNII: 1L4806J2QF) (ADAPALENE - UNII:1L4806J2QF)	ADAPALENE	1 mg in 1 g

Inactive Ingredients

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51316-114-16	1 in 1 CARTON	10/31/2023	
1		45 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:51316-114-05	1 in 1 CARTON	10/31/2023	
2		15 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	ANDA090962	10/31/2023	

Labeler - CVS PHARMACY, INC (062312574)

Revised: 2/2024

CVS PHARMACY, INC