

ADAPALENE- adapalene gel

CVS Pharmacy

Adapalene Gel

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, edetate disodium, methylparaben, poloxamer 182, propylene glycol, purified water, sodium hydroxide

Questions or comments?

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

Principal Display Panel

ADAPALENE GEL

ADAPALENE GEL USP, 0.1%

ACNE TREATMENT

- PREVIOUSLY AVAILABLE ONLY BY PRESCRIPTION
 - FDA-APPROVED
 - DERMATOLOGIST DEVELOPED
 - ONCE DAILY TOPICAL RETINOID*

*Read consumer information leaflet before use

Oil free

Fragrance free

Dermatologist developed and tested

†COMPARE TO THE ACTIVE INGREDIENT IN DIFFERIN® GEL

TAMPER EVIDENT: DO NOT USE IF SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

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

Manufactured by: Glenmark Pharmaceuticals Ltd.

Colvale-Bardez, Goa 403513, India
Distributed By: PL Developments
200 Hicks Street, Westbury, NY 11590

Product Label

TAMPER EVIDENT: DO NOT USE IF SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

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Drug Facts

Active ingredient	Purpose
Adapalene USP 0.1% (retinoid)*	Acne treatment

*read consumer information leaflet

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

If pregnant or breast-feeding, 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 becomes 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 results ■ avoid product contact with 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 are planning to become pregnant while using the product ■ you have symptoms of an allergic reaction (such as itching, rash, hives, swelling of the lips, eyelids, and shortness of breath) ■ irritation becomes severe ■ you see no improvement after 3 months of once daily use

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Questions or comments?
Call 1-877-753-3035 Monday-Friday 9AM-5PM EST

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Manufactured by: Glenmark Pharmaceuticals Ltd.
Colvale-Bardez, Goa 403513, India
Distributed By: PL Developments
200 Hicks Street, Westbury, NY 11590

First FDA-Approved over-the-counter topical retinoid* for acne treatment

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

ADAPALENE GEL

NDC 69842-088-05

ADAPALENE GEL USP, 0.1%

ACNE TREATMENT

- PREVIOUSLY AVAILABLE ONLY BY PRESCRIPTION
- FDA-APPROVED
- DERMATOLOGIST DEVELOPED
- ONCE DAILY TOPICAL RETINOID*

*Read consumer information leaflet before use

Oil free
Fragrance free
Dermatologist developed and tested

Actual Size

NET WT 0.5 OZ (15 g)

***COMPARE TO THE ACTIVE INGREDIENT IN DIFFERIN® GEL**

Lot:

Exp:

3 59726 88805 9

PLD-A578A FC005941

CVS HEALTH Adapalene Gel Acne Treatment

ADAPALENE

adapalene gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69842-088
Route of Administration	TOPICAL		

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)	
METHYL PARABEN (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:69842-088-05	1 in 1 CARTON	08/01/2019	
1		15 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:69842-088-16	1 in 1 CARTON	08/01/2019	
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	ANDA091314	08/01/2019	

Labeler - CVS Pharmacy (062312574)

Revised: 5/2019

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