

ADAPALENE- adapalene gel
P & L Development, LLC

Adapalene Gel USP 0.1 percent ENE 0.5 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 homopolymertype C, edetate disodium, methylparaben, poloxamer 182, propylene glycol, purified water. May contain hydrochloric acid and/or sodium hydroxide to adjust 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
- Once daily topical retinoid*
- Oil free
- fragrance free
- Dermatologist developed and tested

net wt oz (g)

*Read consumer information leaflet before use

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



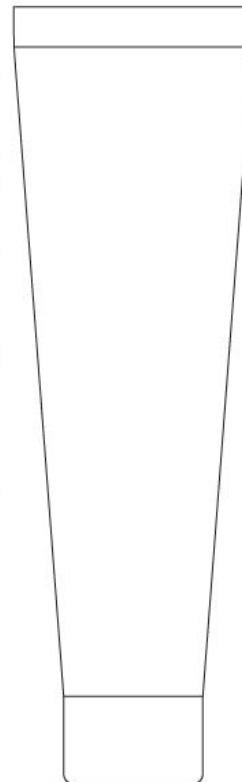
†Compare to the active ingredient in Differin® Gel
NDC 59726-114-05

adapalene
gel USP
0.1%
acne treatment

- previously available only by prescription
- once daily topical retinoid*
- oil free
- fragrance free
- dermatologist developed and tested

*read consumer information leaflet before use

net wt 0.5 oz (15 g)



Actual Size



Distributed by:
PL Developments
200 Hicks Street
Westbury, NY 11590



3 59726 11405 9

PLD-B796A FC008839

Lot No.:

Exp. Date:

READYinCASE Acne Treatment

ADAPALENE

adapalene gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59726-114
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)				
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:59726-114-05	1 in 1 CARTON	11/30/2023	
1		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	11/30/2023	

Labeler - P & L Development, LLC (800014821)