ADAPALENE- adapalene gel Cardinal Health

ADAPALENE

Drug Facts

Active ingredient

Adapalene USP, 0.1% (retinoid) 1

1 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.

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 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

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

- TAMPER EVIDENT: DO NOT USE IF THE SEAL ON THE TUBE IS PUNCTURED OR NOT VISIBLE.
- store at 20° to 25°C (68° to 77°F)[see USP Controlled Room Temperature].
- protect from freezing

Inactive ingredients

carbomer homopolymer type C, edetate disodium, phenoxyethanol, poloxamer 182, propylene glycol, purified water, sodium hydroxide.

Questions?

1-866-923-4914

DISTRIBUTED BY CARDINAL HEALTH DUBLIN, OHIO 43017

PRINCIPAL DISPLAY PANEL - 45 g Tube Carton

LEADER ™

NDC 70000-0666-2

Adapalene Gel USP, 0.1% Acne Treatment COMPARE TO DIFFERIN ® GEL active ingredient †

100% Money Back Guarantee

Previously Available Only by Prescription

FDA Approved

Dermatologist Developed

Once Daily Topical Retinoid*

*Read consumer information leaflet before use

NET WT 1.6 OZ (45 g)



991.91 B293.0 1359

AND EXP DATE PRINT **# TOJ ROJ 9AJJ SIHT** NO COPY / NO COLOR **DA ON \HSINFAV ON**

29 0354 2547112

Drug Facts (continued)

Other information

- TAMPER EVIDENT: DO NOT USE IF THE SEAL ON THE TUBE IS PUNCTURED OR NOT VISIBLE.
- store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

 • protect from freezing

Inactive ingredients carbomer homopolymer type C, edetate disodium, phenoxyethanol poloxamer 182, propylene glycol, purified water, sodium hydro

Questions? 1-966-923-4914

[†]All trademarks are property of their respective owners. This product is not affiliated with the makers/owners of Differin® Gel.

*CardinalHealth™

DISTRIBUTED BY CARDINAL HEALTH www.mvleader.com

1-800-200-6313

Made in Canada

CARDINAL HEALTH, the Cardinal Health LOGO, ESSENTIAL TO CARE, LEADER, and the LEADER LOGO are trademarks or registered tradem of Cardinal Health. All other marks are the property of their respective owners.



Return to place of purchaself not salisfied



LEADER?

Adapalene Gel USP, 0.1%

Acne Treatment

COMPARE TO DIFFERIN® GEL active ingredient

Previously Available Only by Prescription FDA Approved **Dermatologist Developed** Once Dally Topical Retinoid*

*Read consumer information leaflet before use

NET WT 1.6 OZ (45 g)

- Oil free
- Fragrance free Paraben free
- Dermatologist developed and tested
- 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.

Drug Facts

Active ingredient Adapalene USP, 0.1% (retinoid)*.. *read consumer information leaflet

Purpose Acne treatment

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
- 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
- avoid product contact with eyes, lips, and mouth. If contact occurs, immediately flush the area
- wash hands after use

Stop use and ask 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

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

0.125

Acne Treatment

Gel USP, 0.1% Adapalene

LEADER





ADAPALENE

adapalene gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0666
--------------	----------------	--------------------	----------------

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

inactive ingredients		
Ingredient Name	Strength	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)		
EDETATE DISODIUM (UNII: 7FLD91C86K)		
PHENOXYETHANOL (UNII: HIE492ZZ3T)		
POLOXAMER 182 (UNII: JX0HIX6OAG)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
WATER (UNII: 059QF0KO0R)		
SODIUM HYDROXIDE (UNII: 55X04QC32I)		

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:70000- 0666-1	1 in 1 CARTON	03/17/2024			
1		15 g in 1 TUBE; Type 0: Not a Combination Product				
2	NDC:70000- 0666-2	1 in 1 CARTON	03/17/2024			
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	ANDA215940	03/17/2024		

Revised: 3/2024 Cardinal Health