

**ADAPALENE- adapalene gel**  
**Cardinal Health**

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**ADAPALENE**

***Drug Facts***

**Active ingredient**

Adapalene USP, 0.1% (retinoid) <sup>1</sup>

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<sup>1</sup> 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<sup>®</sup> 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)

T325  
B293.0  
19.166

NO VARNISH/NO AQ  
NO COPY / NO COLOR  
THIS FLAP FOR LOT #  
AND EXP DATE PRINT

52  
0324  
524712

**Drug Facts** (continued)

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- TAMPER EVIDENT: DO NOT USE IF THE SEAL ON THE TUBE IS PUNCTURED OR NOT VISIBLE.
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**Questions?** 1-866-923-4914

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



DISTRIBUTED BY CARDINAL HEALTH  
DUBLIN, OHIO 43007  
www.myleader.com  
1-800-200-6303

Essential to Care™ since 1979  
Made in Canada

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Return to place of purchase if not satisfied.



**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)

- 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.

0.125

**Drug Facts**

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

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Adapalene Gel USP, 0.1%  
Acne Treatment

LEADER™



# ADAPALENE

adapalene gel

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70000-0666
<b>Route of Administration</b>	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)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
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: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	

**Labeler** - Cardinal Health (063997360)

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## Establishment

Name	Address	ID/FEI	Business Operations
Sun Pharma Canada Inc.		243339023	manufacture(70000-0666)

Revised: 7/2025

Cardinal Health