

**ADAPALENE- adapalene gel**  
**Topco Associates**

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**Adapalene Gel 0.1 percent 0.5**

**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, methylparabem, poloxamer 182, propylene glycol, purified water

May contain hydrochloric acid and /or sodium hydroxide to adjust pH.

### **Questions or comments?**

Call toll free **1-888-423-0139**

### **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\*
- Dermatologist developed & tested

OIL & FRAGRANCE FREE

\*Read consumer information leaflet before use

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

DISTRIBUTED BY TOPCO

ASSOCIATES LLC

ITASCA, IL 60143

**Product Label**

**Drug Facts**

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

**Use** ■ For the treatment of acne

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NDC 76162-114-05



**ADAPALENE  
 GEL USP 0.1%  
 ACNE TREATMENT**

- Oil free
- Fragrance free
- Dermatologist developed & tested

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

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

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 ITASCA, IL 60143  
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 QUESTIONS? 1-888-423-0139  
 topcare@topco.com  
 www.topcarebrand.com



Scan here for more information or call 1-888-423-0139

**QUALITY GUARANTEED**

This TopCare® product is laboratory tested to guarantee its highest quality. Your total satisfaction is guaranteed.



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 GEL USP 0.1%  
 ACNE TREATMENT**

Compare to the active ingredient in DIFFERIN® GEL†

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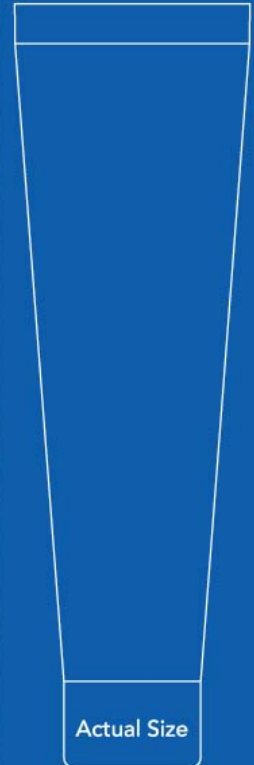
\* Read consumer information leaflet before use

OIL & FRAGRANCE FREE

NET WT 0.5 OZ (15 g)

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.



One Tube Inside



PLD-A796A FC008842

Lot No.:

Exp. Date:

**TOP CARE BEAUTY Acne Treatment**

**ADAPALENE**

adapalene gel

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:76162-114
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

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

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:76162-114-05	1 in 1 CARTON	11/30/2023	
1		15 g in 1 TUBE; Type 0: Not a Combination Product		

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ANDA	ANDA090962	11/30/2023	

**Labeler** - Topco Associates (006935977)

Revised: 3/2024

Topco Associates