

**ADAPALENE- adapalene gel**  
**TOP CARE (Topco Associates LLC)**

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**Adapalene Gel USP 0.1 percent**

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

### **Questions or comments?**

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

### **Principal Display Panel**

TopCare beauty™

ADAPALENE GEL USP, 0.1%

ACNE TREATMENT

Compare to Differin® GEL active ingredient\*

- Previously available only by prescription
- FDA-approved
- Dermatologist developed
- Once daily topical retinoid\*

Oil free & Fragrance free

Dermatologist developed and tested

\*Read consumer information leaflet before use

**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.

DISTRIBUTED BY TOPCO ASSOCIATES LLC

ELK GROVE VILLAGE, IL 60007

[www.topcarebrand.com](http://www.topcarebrand.com)

**Product Label**

**Drug Facts**

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

**Purpose**

**Use** ■ For the treatment of acne

**Warnings**  
For external use only

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If pregnant or breast-feeding, ask a doctor before use.

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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.



Actual Size  
One Tube Inside

NDC 36800-088-05

**TopCare beauty™**

**ADAPALENE GEL USP, 0.1% ACNE TREATMENT**

Compare to DIFFERIN® GEL active ingredient\*

- † Previously available only by prescription
- † FDA approved
- † Dermatologist developed & tested
- † Once daily topical retinoid‡

‡ Read consumer information leaflet before use

OIL & FRAGRANCE FREE

NET WT 0.5 OZ (15 g)

**TopCare beauty™**

**ADAPALENE GEL USP, 0.1% ACNE TREATMENT**

- † Oil free
- † Fragrance free
- † Dermatologist developed & tested

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KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

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ELK GROVE VILLAGE, IL 60007  
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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



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

**TOPCARE beauty Adapalene Gel Acne Treatment**

**ADAPALENE**

adapalene gel

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:36800-088
<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:36800-088-05	1 in 1 CARTON	07/30/2020	
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	ANDA091314	07/30/2020	

**Labeler** - TOP CARE (Topco Associates LLC) (006935977)

Revised: 11/2022

TOP CARE (Topco Associates LLC)