

**PROACTIV MD ADAPALENE ACNE TREATMENT- adapalene gel**  
**Alchemee, LLC**

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**Proactiv MD® Adapalene Gel 0.1%**  
**Acne Treatment**

***Drug Facts***

**Active ingredient**

Adapalene 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 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

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center 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°- 77°F
- protect from freezing

### **Inactive ingredients**

carbomer 940, edetate disodium, methylparaben, poloxamer 182, propylene glycol, purified water and sodium hydroxide. May contain hydrochloric acid to adjust pH.

### **Questions?**

1-866-735-4137

Distributed by The Proactiv Company LLC  
100 N Sepulveda Blvd., El Segundo, CA 90245

### **PRINCIPAL DISPLAY PANEL - 15 g Tube Box**

**proactiv** MD®

**ADAPALENE GEL 0.1%**  
**ACNE TREATMENT**

First FDA-Approved  
Over-the-Counter  
Topical Retinoid\* for

Acne Treatment

Previously Available  
Only By Prescription

Dermatologist  
Developed and Tested

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

NET WT 0.5 OZ (15 g)

## Drug Facts

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\*read consumer information leaflet

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## Drug Facts (continued)

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### Questions?

1-800-950-4695

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100 N Sepulveda Blvd., El Segundo, CA 90245  
proactiv.com  
Made in Canada  
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proactiv MD.

ADAPALENE GEL 0.1%  
ACNE TREATMENT

Once Daily  
Topical Retinoid\*

\*Read consumer information leaflet before use.

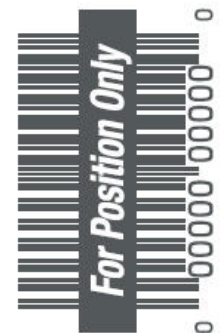
First FDA-Approved  
Over-the-Counter  
Topical Retinoid\* for  
Acne Treatment

Previously Available  
Only By Prescription

Dermatologist  
Developed and Tested

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Oil Free  
Fragrance Free  
FDA Approved



NET WT 0.5 OZ (15 g)

PAJ01239



# PROACTIV MD ADAPALENE ACNE TREATMENT

adapalene gel

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:11410-956
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Adapalene</b> (UNII: 1L4806J2QF) (Adapalene - UNII:1L4806J2QF)	Adapalene	0.1 g in 100 g

## Inactive Ingredients

Ingredient Name	Strength
<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

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11410-956-44	1 in 1 BOX	03/27/2017	
1		15 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:11410-956-17	1 in 1 BOX	03/27/2017	
2		45 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:11410-956-38	1 in 1 BLISTER PACK	08/09/2017	
3		2 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
NDA AUTHORIZED GENERIC	NDA020380	03/27/2017	

**Labeler** - Alchemee, LLC (080216357)

### Establishment

Name	Address	ID/FEI	Business Operations
G Production Inc		251676961	manufacture(11410-956)

Revised: 11/2022

Alchemee, LLC