

**ADAPALENE GEL- adaplaene gel**  
**Acne Free LLC**

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**Adapalene Gel 15g**

**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

**If pregnant or breast-feeding**

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**

• 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. Adults and children 12 years of age and older:

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

carbomer homopolymer, edetate disodium, phenoxyethanol, poloxamer 182, propylene glycol, purified water and sodium hydroxide

### **Questions or comments**

1-800-768-2913

EXUPERY DESIGN

2H23 Adapalene Gel Paraben Free 15g  
 UPC: 850004234563

**FONTS:**  
 Brandon Grotesque Light  
 Brandon Grotesque Regular  
 Brandon Grotesque Medium  
 Brandon Grotesque Bold  
 Helvetica Neue LT Std 52 Condensed  
 Helvetica Neue LT Std 77 Bold Condensed  
 Helvetica Neue LT Std 77 Bold Condensed Oblique

PMS 1495C GLOSS VARNISH  
 PMS 7460C DIELINE  
 PMS 432 C  
 METALLIC PMS 284  
 PMS 286 C  
 CMYK



TEMPLE PACKAGING PVT LTD

Customer: GLENMARK	Separations for Knives used
Description: Adapalene 15g - 50x38x135mm	Cut _____
Design: D1219_006 ADAPALENE 50X38X135.ARD	Crease _____
Design No: D1219_006	10 10 cut & crease _____
L x W x D: 50 x 38 x 182	Area: 45969.3 sqmm
Grain/corr: Horizontal	Side shown: Printed side
Board: Saffire Graphic	
Reason for Revision:	
1 Area 2 Area 3 Area 4 Area 5 Area 6 Area 7 Area 8 Area 9 Area 10 Area	
* ALL UNITS ARE IN MM *	
Designer: Ganesh Nangare	Date: 08/12/22

**ADAPALENE GEL**

adaplaene gel

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:80861-114
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ADAPALENE (UNII: 1L4806J2QF) (ADAPALENE - UNII:1L4806J2QF)	ADAPALENE	0.00036 g in 1 g

**Inactive Ingredients**

Ingredient Name	Strength
CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)	

**Product Characteristics**

Color	white (clear, transparent)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80861-114-01	1 g in 1 TUBE; Type 0: Not a Combination Product	12/20/2023	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091314	12/20/2023	

**Labeler** - Acne Free LLC (122237140)**Establishment**

Name	Address	ID/FEI	Business Operations
Glenmark Pharmaceuticals Limited		677318665	manufacture(80861-114)

Revised: 1/2024

Acne Free LLC