

ADAPALENE- adaplane 0.1% gel
Acne Free, LLC

Adapalene 45g

Adapalene USP 0.1% (retinoid)*

Purpose

Acne treatment

Use

for the treatment of acne

Warnings

For external use only

- on damaged skin (cuts, abrasions, eczema, sunburn)
- if you are allergic to adapalene or any of the ingredients in this product

ask a doctor before use

When using this product

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 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. • Adults and children 12 years of age and older: • 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, phenoxyethanol, poloxamer 182, propylene glycol, purified water and sodium hydroxide

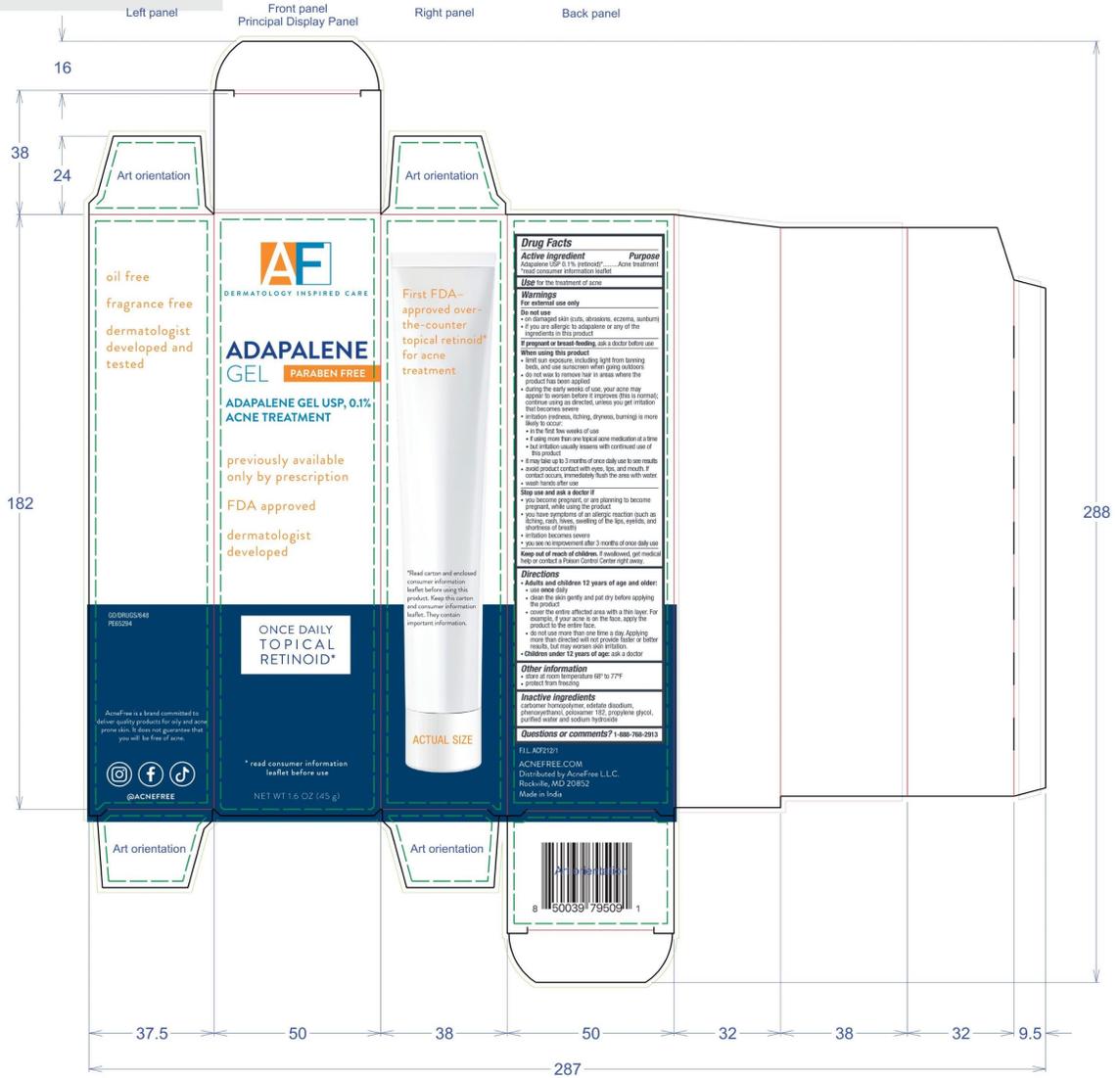
Questions or comments?

1-888-768-2913

EXUPERY DESIGN

2H23 Adapalene Gel Paraben Free 45g
 UPC: 850039795091

FONTS:
 Brandon Grotesque Light
 Brandon Grotesque Regular
 Brandon Grotesque Medium
 Brandon Grotesque Bold
 Helvetica Neue LT Std 57 Condensed
 Helvetica Neue LT Std 77 Bold Condensed
 Helvetica Neue LT Std 77 Bold Condensed Oblique



TEMPLE PACKAGING PVT LTD

Customer: GLENMARK	Separations for Knives used
Description: Adapalene 45g - 50x38x182mm	Cut _____
Design: D1219_007 ADAPALENE 50X38X182.ARD	Crease _____
Design No: D1219_007 Version No: 01	10 10 cut & crease _____
L x W x D: 50 x 38 x 182 Area: 59458.3 sqmm	
Grain/corr: Horizontal Side shown: Printed side	
Board: Saffire Graphic 300	
Reason for Revision:	
* ALL UNITS ARE IN MM *	Designer: Ganesh Nangare
	Date: 08/12/22

** KLD FOR DIMENSIONAL REF. ONLY **

ADAPALENE
 adaplane 0.1% gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80861-115
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ADAPALENE (UNII: 1L4806J2QF) (ADAPALENE - UNII:1L4806J2QF)	ADAPALENE	0.1 g in 1 g

Inactive Ingredients

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

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80861-115-01	1 g in 1 TUBE; Type 0: Not a Combination Product	01/05/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091314	01/05/2024	

Labeler - Acne Free, LLC (122237140)

Establishment

Name	Address	ID/FEI	Business Operations
Glenmark Pharmaceuticals		677318665	manufacture(80861-115)