# ADAPALENE- adapalene gel Safeway, Inc.

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# Adapalene Gel USP 0 1 percent ENE 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

# 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 become severe
- irritation (redness, itching, dryness, burning) is more likely to occur:
  - in the first few weeks of use
  - o 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 month. 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 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 (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 in 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 rooms temperature 68º to 77ºF
- protect from freezing

# Inactive ingredients

carbomer homopolymer type 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 1-877-753-3935 Monday-Friday 9AM-5PM EST

# **Principal Display Panel**

COMPARE TO Differin® Gel active ingredient\*\*

ADAPALENE GEL USP 0.1%

#### ACNE TREATMENT

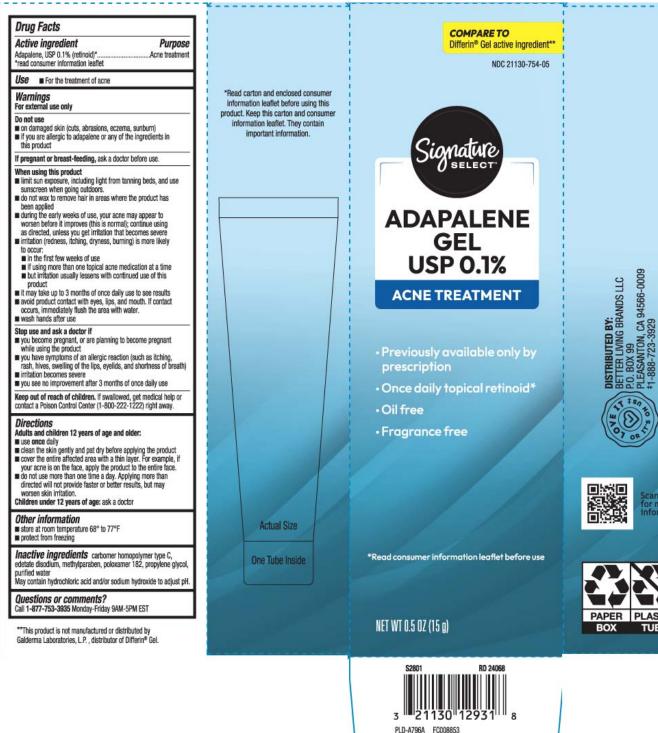
- Previously available only by prescription
- Once daily topical retinoid\*
- Oil free
- fragrance free

# NET WT OZ (g)

- \*Read consumer information leaflet before use
- \*Read carton and enclosed consumer information leaflet before using this product. Keep this carton and consumer information leaflet. They contain important information.
- \*\*This product is not manufactured or distributed by Galderma Laboratories, L.P., distributor of Differin $^{\circledR}$  Gel.

DISTRIBUTED BY
BETTER LIVING BRANDS LLC
P.O. BOX 99
PLEASANTON, CA 94566-0009

### **Product Label**







### **ADAPALENE**

adapalene gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21130-754
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ADAPALENE (UNII: 1L4806J2QF) (ADAPALENE - UNII:1L4806J2QF)	ADAPALENE	1 mg in 1 g	

Inactive Ingredients		
Ingredient Name	Strength	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)		
EDETATE DISODIUM (UNII: 7FLD91C86K)		
METHYLPARABEN (UNII: A2I8C7HI9T)		
POLOXAMER 182 (UNII: JX0HIX6OAG)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
WATER (UNII: 059QF0KO0R)		
SODIUM HYDROXIDE (UNII: 55X04QC32I)		
HYDROCHLORIC ACID (UNII: QTT17582CB)		

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:21130-754- 05	1 in 1 CARTON	01/31/2024			
1		15 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	
ANDA	ANDA090962	01/31/2024		

# Labeler - Safeway, Inc. (009137209)

Revised: 3/2024 Safeway, Inc.