ADAPALENE- adapalene gel The Kroger Co.

Adapalene Gel USP 0 1 percent ENE

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 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 the 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 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 **1-800-632-6900**

Principal Display Panel

Compare to the Active Ingredient in Differin® Gel[†]

ADAPALENE GEL USP 0.1%

acne treatment

ONCE DAILY TOPICAL RETINOID*

Oil & fragrance free

dermatologist developed & tested

previously available only by prescription

*READ CONSUMER INFORMATION LEAFLET BEFORE USE

NET WT OZ (g)

*READ CARTON AND ENCLOSED CONSUMER INFORMATION LEAFLET BEFORE USING THIS PRODUCT.

KEEP THIS CARTON AND CONSUMER INFORMATION LEAFLET. THEY CONTAIN IMPORTANT INFORMATION.

[†]DIFFERIN[®] GEL IS A REGISTERED TRADEMARK OF GALDERMA LABORATORIES, L.P., DALLAS, TX 75201.

GALDERMA LABORATORIES, L.P. IS NOT AFFILIATED WITH THE KROGER CO. OR THIS PRODUCT.

DISTRIBUTED BY THE KROGER CO.

CINCINNATI, OHIO 45202

Product Label



adapalene gel

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:30142-725

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: A218C7HI9T)			
POLOXAMER 182 (UNII: JX0HIX6OAG)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
WATER (UNII: 059QF0KO0R)			
SODIUM HYDROXIDE (UNII: 55X04QC32I)			
HYDROCHLORIC ACID (UNII: QTT17582CB)			

Packaging					
# Item Code	Package Description	Marketing Start Date	Marketing End Date		
NDC:30142-725- 05	1 in 1 CARTON	03/15/2024			
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	03/15/2024	

Labeler - The Kroger Co. (006999528)

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