

ADAPALENE- adapalene gel
Topco Associates

Adapalene Gel 0.1 percent 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

Pregnancy/Breastfeeding,

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
 - 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 result
- 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 this 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 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° to 77°F
- protect from freezing

Inactive ingredients

carbomer homopolymertype 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 toll free **1-888-423-0139**

Principal Display Panel

Compare to the active ingredient in DIFFERIN® GEL†

ADAPALENE GEL USP 0.1%

ACNE TREATMENT

- Previously available only by prescription
- FDA approved
- Dermatologist developed
- Once daily topical retinoid*

OIL free

Fragrance free

Dermatologist development & tested

*Read consumer information leaflet before use

*This product is not manufactured or distributed by Galderma Laboratories, L.P.
distributor of Differin® Gel.

TAMPER EVIDENT: DO NOT USE IF SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

DISTRIBUTED BY TOPCO

ASSOCIATES LLC

ITASCA, IL 60143

Product Label

NDC 76162-114-05

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

Drug Facts

Active ingredient Purpose
 Adapalene, USP 0.1% (retinoid)* Acne treatment
 *read consumer information leaflet

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
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**ADAPALENE
 GEL USP 0.1%
 ACNE TREATMENT**

- ★ Oil free
- ★ Fragrance free
- ★ Dermatologist developed & tested

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KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

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 QUESTIONS? 1-888-423-0139
 topcare@topco.com
 www.topcarebrand.com



Scan here for more information or call 1-888-423-0139

QUALITY GUARANTEED

This TopCare® product is laboratory tested to guarantee its highest quality. Your total satisfaction is guaranteed.



**ADAPALENE
 GEL USP 0.1%
 ACNE TREATMENT**

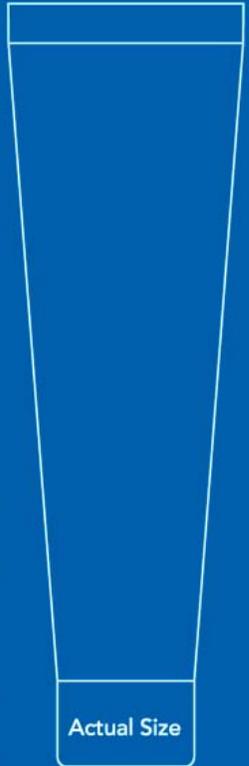
Compare to the active ingredient in DIFFERIN® GEL¹

- ★ Previously available only by prescription
- ★ FDA approved
- ★ Dermatologist developed
- ★ Once daily topical retinoid*

*Read consumer information leaflet before use

**OIL &
 FRAGRANCE
 FREE**

NET WT 0.5 OZ (15 g)



Actual Size

One Tube Inside



PLD-B7968 FC009560

Lot No.:

Exp. Date:

TOPCARE BEAUTY Acne Treatment

ADAPALENE

adapalene gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76162-114
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: 059QF0K00R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76162-114-05	1 in 1 CARTON	11/30/2023	
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	11/30/2023	

Labeler - Topco Associates (006935977)

Revised: 10/2025

Topco Associates