

ADAPALENE GEL 0.1%- adapalene gel 0.1% gel
MOHNARK PHARMACEUTICALS INC

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Adapalene Gel 0.1% Acne Treatment

ACTIVE INGREDIENT

Adapalene (retinoid) 0.1%

INACTIVE INGREDIENTS

Inactive ingredients:

Carbopol 980, edetate disodium, benzyl alcohol, Poloxamer 124, Propylene Glycol, Purified Water, Sodium Hydroxide

PURPOSE

Acne Treatment

WARNINGS

For external use only

USES

For the treatment of acne

DO NOT USE

- on damaged skin (cuts, abrasions, eczema, sunburn)
- If you are allergic to adapalene or any of the ingredients in 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 irritation that becomes severe
- irritation (redness, itching, dryness, burning) is more likely to occur
- in the first few weeks of use
- if using more 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 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 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 right away

DIRECTIONS

Adults and children 2 years 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 results or better results, but may worsen skin irritation.

Children under 12 years of age ask a doctor

OTHER INFORMATION

- Store at USP controlled room temperature 20 - 25 °C (68 - 77 °F)
- protect from freezing

INDICATIONS AND USAGE

Adapalene is a topical retinoid used for treating acne vulgaris

DOSAGE AND ADMINISTRATION

Apply a thin film of Adapalene Gel, 0.1% to the entire face and any other affected areas of the skin once daily in the evening, after washing gently with a non-medicated soap.

For topical use only. Not for ophthalmic, oral or intravaginal use.

PRINCIPAL DISPLAY PANEL

Carton Label - NDC 73715-003-01

Adapalene Gel, 0.1%

For external use only

Once daily Topical Acne Treatment

Net Wt 1 oz (30 grams)

<p>Drug Facts</p> <p><i>Active Ingredients</i> <i>Purpose</i> Adapalene USP 0.1%.....Acne treatment (retinoid)* * read product directions before use</p> <p>Uses • for the treatment of acne</p> <p>Warnings For external use only.</p> <p>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.</p> <p>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 • 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 area with water. • wash hands after use</p> <p>Stop use and ask a doctor if • you become pregnant, or are planning to become pregnant, while using this product</p>	<p>Drug Facts cont'd</p> <p>• 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</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p>Directions Adults and children 2 years 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 once 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</p> <p>Other information • Store at USP controlled room temperature 20-25°C (68-77°F). • protect from freezing</p> <p>Inactive ingredients carbopol 980, edetate disodium, benzyl alcohol, poloxamer 124, propylene glycol, purified water and sodium hydroxide.</p> <p>Manufactured by: Mohnark Pharmaceuticals, Inc. Questions or comments? Toll free: 1-866-611-5206</p> <p>C47214</p>	<p>ADVANCE RETINOID TREATMENT</p> <p>ADAPALENE GEL 0.1%</p> <p>ACNE TREATMENT</p> <p>Once daily Topical Acne Treatment</p> <p> PARABEN FREE</p> <p>Previously available only by prescription.</p> <p>Once Daily Topical Retinoid* *Read product directions before use</p> <p>For External Use Only. NOT FOR OPHTHALMIC USE</p> <p>NET WT. 1 OZ (30 grams)</p>	<p>• Close cap tightly between uses. • Retain carton for complete information. • Package contains one tube. • Convenient travel size</p> <p> MADE IN USA</p> <p> MOHNARK Pharmaceuticals, Inc.</p> <p> 8 60002 32492 0</p>
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ADAPALENE GEL 0.1%

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73715-003
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 100 g

Inactive Ingredients

Ingredient Name	Strength
CARBOMER 980 (UNII: 4Q93RCW27E)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
POLOXAMER 124 (UNII: 1S66E28KXA)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73715-003-01	30 g in 1 TUBE; Type 0: Not a Combination Product	09/30/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		09/30/2024	

Labeler - MOHNARK PHARMACEUTICALS INC (117013830)

Revised: 7/2025

MOHNARK PHARMACEUTICALS INC