

**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.*

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**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><b>Drug Facts</b></p> <p><b>Active Ingredients</b>      <b>Purpose</b> Adapalene USP 0.1%.....Acne treatment (retinoid)* * read product directions before use</p> <p><b>Uses</b> • for the treatment of acne</p> <p><b>Warnings</b> For external use only.</p> <p><b>Do not use</b> • 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><b>When using this product</b> • 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><b>Stop use and ask a doctor if</b> • you become pregnant, or are planning to become pregnant, while using this product</p>	<p><b>Drug Facts cont'd</b></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><b>Directions</b> 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><b>Other information</b> • Store at USP controlled room temperature 20-25°C (68-77°F). • protect from freezing</p> <p><b>Inactive ingredients</b> 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><b>ADVANCE RETINOID TREATMENT</b></p> <p><b>ADAPALENE GEL 0.1%</b></p> <p>ACNE TREATMENT</p> <p>Once daily Topical Acne Treatment</p> <p> <b>PARABEN FREE</b></p> <p>Previously available only by prescription.</p> <p>Once Daily Topical Retinoid* *Read product directions before use</p> <p>For External Use Only. <b>NOT FOR OPHTHALMIC USE</b></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> <b>MOHNARK</b> Pharmaceuticals, Inc.</p> <p> 8 60002 32492 0</p>
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# ADAPALENE GEL 0.1%

adapalene gel 0.1% gel

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:73715-003
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
ADAPALENE (UNII: 1L4806J2QF) (ADAPALENE - UNII:1L4806J2QF)	ADAPALENE	0.1 g in 100 g

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
CARBOMER 980 (UNII: 4Q93RCW27E)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
POLOXAMER 124 (UNII: 1S66E28KXA)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

## Packaging

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

## Marketing Information

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

**Labeler** - MOHNARK PHARMACEUTICALS INC (117013830)

Revised: 9/2024

MOHNARK PHARMACEUTICALS INC