

**ADAPALENE- adapalene gel**  
**L'Oreal USA Products Inc**

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**Drug Facts**

**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 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
  - 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 the area with water.
  - wash hands after use

**Stop use and ask doctor if**

- you become pregnant, or are 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 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 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°-77°F
- protect from freezing

## **Inactive Ingredients**

carbomer homopolymer, edetate disodium, methylparaben, poloxamer 182, propylene glycol, purified water and sodium hydroxide

## **Questions or comments?**

**1-888-768-2913**

## **Patent Leaflet**

**ADAPALENE GEL USP, 0.1%**

**ACNE TREATMENT**

## **Frequently Asked Questions**

**What is adapalene gel 0.1% and what is it used for?**

Adapalene gel 0.1% is a topical retinoid medication used for the treatment of acne in people age 12 years and older.

Use only one time a day.

### **What should I know before using the product?**

**If pregnant or breast-feeding**, ask a doctor before use.

Some other retinoid drugs have been shown to cause birth defects. There is no specific evidence that adapalene gel 0.1% causes birth defects in humans when used topically as directed.

**Do not use** adapalene gel 0.1% if you are allergic to adapalene or any of the ingredients in this product.

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

### **How often do I apply the product?**

Apply this product **only one time a day** and try to apply the product at the same time each day.

### **How do I apply the product?**

Gently clean the affected areas using a mild (non-irritating) cleanser and pat dry. Apply adapalene gel 0.1% as a thin layer to the affected areas of the skin **only one time a day**. For example, if you get acne on the face, clean, dry and apply the product to the entire face. Adapalene gel 0.1% is **not** a spot treatment and should not be used to treat a single pimple.

Avoid product contact with eyes, lips and mouth. **If contact occurs, immediately flush the area with water.**

Do not apply product to damaged skin (cuts, abrasions, eczema, or sunburn). Wash hands after use.

### **How long will it take for adapalene gel 0.1% to work?**

It may take up to 3 months of daily use for results to appear.

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.

### **What do I do if I need to be in the sun?**

When possible, limit sun exposure, including light from tanning beds.

When going outdoors, use a sunscreen as labeled. Your skin may be more sensitive while using adapalene gel 0.1%. If you use this product during the day, allow it to dry before applying sunscreen.

### **Can I use a moisturizer if my skin is dry?**

Yes, use of a moisturizer may help decrease dryness and other signs of irritation. Avoid products containing alpha hydroxy or glycolic acids which may worsen irritation.

### **When is my skin most likely to become irritated? And what do I do?**

Irritation (redness, itching, dryness, burning) is more likely to occur:

In the first few weeks of use.

if using abrasive skin cleansers, products with drying effects or more than one topical acne medication at a time. You may want to delay starting adapalene gel 0.1% until any irritation from using the other product(s) has gone away.

Moisturizers may be used.

Irritation usually lessens after 4 weeks of continued use.

### **What do I do if my skin becomes severely irritated?**

If irritation becomes severe (overly bothersome), stop use and ask a doctor before using the product again.

### **Can I remove unwanted facial hair by waxing while using this product?**

Do not use wax to remove hair in areas where the product has been applied because it may worsen skin irritation.

### **What ingredients are used in adapalene gel 0.1%?**

Adapalene gel 0.1% contains:

1. The active ingredient is adapalene 0.1%. The other ingredients are: carbomer homopolymer, edetate disodium, methylparaben, poloxamer 182, propylene glycol, purified water, and sodium hydroxide.

### **How should I store this product?**

Adapalene gel 0.1% should be stored at room temperature [68° to 77°F]. Protect from freezing.

Do not use the product after the expiry date marked on the crimp of the tube.

### **Other Questions? Where can I get more information?**

**Phone: 1-888-768-2913**

**May 2018**

### **Package/Label Principal Display Panel**



PE498001118-1

Non varnished Zone

First FDA-approved over-the-counter topical retinoid\* for acne treatment

oil free

fragrance free

dermatologist developed and tested

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

ACTUAL SIZE

### Drug Facts

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

**Use** for the treatment of acne

#### Warnings

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- 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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### Drug Facts (continued)

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ask a doctor

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#### Questions or comments?

1-888-768-2913

GO/DRUGS/648

AcneFree is a brand committed to deliver quality products for oily and acne prone skin. It does not guarantee that you will be free of acne.

ACNEFREE.COM  
AcneFree LLC,  
New York, NY 10001  
Made in India  
5000000008499



@ACNEFREE



DERMATOLOGY INSPIRED CARE

# ADAPALENE GEL

ADAPALENE GEL USP, 0.1%  
ACNE TREATMENT

previously available  
only by prescription

FDA approved

dermatologist developed

ONCE DAILY  
TOPICAL  
RETINOID\*

\* read consumer information leaflet before use

NET WT 0.5 OZ (15 g)



3 606000 154031 6



# ADAPALENE

adapalene gel

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:49967-354
<b>Route of Administration</b>	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)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49967-354-02	1 in 1 CARTON	09/18/2019	
1		15 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:49967-354-01	1 in 1 CARTON	11/29/2019	
2		45 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	ANDA091314	09/18/2019	

**Labeler** - L'Oreal USA Products Inc (002136794)

## Establishment

Name	Address	ID/FEI	Business Operations
Glenmark Pharmaceuticals Limited		677318665	MANUFACTURE(49967-354) , ANALYSIS(49967-354)

Revised: 11/2019

L'Oreal USA Products Inc