

EFFACLAR- adapalene gel
L'Oreal USA Products Inc

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-LRP-LABO 1-888-577-5226

Monday – Friday (9 a.m – 5 p.m EST)

Patent Leaflet

EFFACLAR

ADAPALENE GEL 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:
 - o In the first few weeks of use.
 - o 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:

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° -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) 577 - 5226**

Principal Display Panel



PES9S961019-1

OIL-FREE
FRAGRANCE-FREE
DERMATOLOGIST
DEVELOPED AND TESTED

LA ROCHE-POSAY
LABORATOIRE DERMATOLOGIQUE

ONCE DAILY
TOPICAL RETINOID*

EFFACLAR
ADAPALENE GEL 0.1%
ACNE TREATMENT

DERMATOLOGIST
DEVELOPED AND TESTED

PREVIOUSLY AVAILABLE
ONLY BY PRESCRIPTION

FDA APPROVED
OIL-FREE. FRAGRANCE-FREE

* Read consumer information leaflet
before use

NET WT. 1.6 OZ (45g)

ACTUAL
SIZE

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.

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 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.

*Read carton and enclosed consumer information leaflet before using this product.

Keep this carton and consumer information leaflet. They contain important information.



3 606000 527553

1

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

- 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 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 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-LRP-LABO 1-888-577-5226
Monday - Friday 9 a.m. - 5 p.m. EST

942124

00DRUGS#48

Distribution reserved to La Roche-Posay agreed distributors
La Roche-Posay LLC,
10 Hudson Yards, New York, NY 10001
La Roche-Posay Laboratoire Dermatologique
CAI 86270 La Roche-Posay,
TSA 75000 93584 ST OUEN CEDEX FR
www.laroche-posay.us
Made in India 5000000018817

NO VARNISH ZONE



EFFACLAR

adapalene gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49967-591
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: 059QF0KO0R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49967-591-02	1 in 1 CARTON	10/22/2019	
1		3 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:49967-591-01	1 in 1 CARTON	08/23/2019	
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	08/23/2019	

Labeler - L'Oreal USA Products Inc (002136794)

Establishment

Name	Address	ID/FEI	Business Operations
Glenmark Pharmaceuticals Limited		677318665	MANUFACTURE(49967-591) , ANALYSIS(49967-591)

Revised: 8/2019

L'Oreal USA Products Inc