

ADAPALENE- adapalene gel
GLENMARK THERAPEUTICS INC., USA

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 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 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°F to 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) 721-7115

Patient 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 breastfeeding**, 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.

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.

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.

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° 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) 721-7115

February 2022

Package/Label Principal Display Panel

NDC 72657-102-17

Adapalene Gel USP, 0.1%

NET WT. 0.5 OZ (15 g)

**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	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 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 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 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.

Drug Facts (continued)

- 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°F to 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) 721-7115

Distributed by:
Glenmark Therapeutics Inc., USA
Mahwah, NJ 07430
www.glenmarkpharma-us.com
Made in India
GO/DRUGS/648
02/22
*This product is not manufactured or distributed by Galderma Laboratories, L.P. and/or Galderma Holding S.A., distributor of DIFFERIN® Gel and owner of the registered trademark DIFFERIN® respectively. [Galderma does not make or license Glenmark's product.]

NDC 72657-102-17

**ADAPALENE
GEL**

Adapalene Gel USP, 0.1%

**ACNE
TREATMENT**

†Compare to the active ingredient of Differin®

**ONCE DAILY
TOPICAL
RETINOID***

Previously available only by prescription

FDA approved
Dermatologist developed

*Read consumer information leaflet before use

glenmark
Therapeutics▲

NET WT. 0.5 OZ (15 g)

Package/Label Principal Display Panel

NDC 72657-102-55

Adapalene Gel USP, 0.1%

NET WT. 1.6 OZ (45 g)

NDC 72657-102-55

ADAPALENE GEL

Adapalene Gel USP, 0.1%

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

ACNE TREATMENT

†Compare to the active ingredient of Differin®

ONCE DAILY TOPICAL RETINOID*

Previously available only by prescription

FDA approved
Dermatologist developed

*Read consumer information leaflet before use

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

ACTUAL SIZE



NET WT. 1.6 OZ (45 g)

OIL FREE
FRAGRANCE FREE
DERMATOLOGIST DEVELOPED AND TESTED



www.glenmarkpharma-us.com

Drug Facts

Active ingredient Adapalene, USP 0.1% (retinoid)* **Purpose** 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 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 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 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°F to 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) 721-7115

Distributed by: Glenmark Therapeutics Inc., USA
Mahwah, NJ 07430
Made in India
GQ/DRUGS/648
02/22

*This product is not manufactured or distributed by Galderma Laboratories, L.P. and/or Galderma Holding S.A., distributor of DIFFERIN® Gel and owner of the registered trademark DIFFERIN,® respectively. [Galderma does not make or license Glenmark's product.]

ADAPALENE

adapalene gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72657-102
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)	
POLOXAMER 182 (UNII: JX0HIX6OAG)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
METHYLPARABEN (UNII: A2I8C7HI9T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72657-102-17	1 in 1 CARTON	01/01/2023	
1		15 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:72657-102-55	1 in 1 CARTON	01/01/2023	
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	01/01/2023	

Labeler - GLENMARK THERAPEUTICS INC., USA (969085666)

Establishment

Name	Address	ID/FEI	Business Operations
Glenmark Pharmaceuticals Limited		677318665	MANUFACTURE(72657-102) , ANALYSIS(72657-102)

Revised: 6/2023

GLENMARK THERAPEUTICS INC., USA