

DIFFERIN - adapalene gel
Galderma Laboratories, L.P.

DIFFERIN® GEL
ADAPALENE GEL, 0.1%

Drug Facts

Active ingredient

Adapalene 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 940, edetate disodium, methylparaben, poloxamer 182, propylene glycol, purified water and sodium hydroxide.
May contain hydrochloric acid to adjust pH.

Questions? 1-866-735-4137

Patient Leaflet

**DIFFERIN GEL
ADAPALENE GEL 0.1%
ACNE TREATMENT**

Frequently Asked Questions**What is Differin Gel and what is it used for?**

- Differin Gel is a topical retinoid medication used for the treatment of acne in people 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 Differin Gel 0.1% causes birth defects in humans when used topically as directed.
- **Do not use** Differin Gel 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 Differin Gel 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. Differin Gel 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 Differin Gel 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.

DIFFERIN GEL

ADAPALENE GEL 0.1%

ACNE TREATMENT

Frequently Asked Questions (Continued)

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 when using Differin Gel. 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 hydroxyl 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 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 Differin Gel 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 Differin?

- Differin Gel contains:

The active ingredient is adapalene 0.1%. The other ingredients are: carbomer 940, edetate disodium, methylparaben, poloxamer 182, propylene glycol, purified water, and sodium hydroxide. May contain hydrochloric acid to adjust pH.

How should I store this product?

- Differin Gel should be stored at room temperature [68° - 77°]. Protect from freezing.
- Do not use the product after the expiry date marked on the packaging.

Other Questions? Where can I get information?

Phone: 1-866-735-4137

P56836-0



DIFFERIN[®] GEL

ADAPALENE GEL 0.1%

ACNE TREATMENT

Frequently Asked Questions

What is Differin Gel and what is it used for?

- Differin Gel 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 Differin Gel 0.1% causes birth defects in humans when used topically as directed.
- **Do not use** Differin Gel 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 Differin Gel 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. Differin Gel 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 Differin Gel 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.



DIFFERIN[®] GEL

ADAPALENE GEL 0.1%

ACNE TREATMENT

Frequently Asked Questions (Continued)

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 Differin Gel. 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 Differin Gel 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 Differin Gel?

- Differin Gel contains:
The active ingredient is adapalene 0.1%. The other ingredients are: carbomer 940, edetate disodium, methylparaben, poloxamer 182, propylene glycol, purified water, and sodium hydroxide. May contain hydrochloric acid to adjust the pH.

How should I store this product?

- Differin Gel should be stored at room temperature [68° – 77°F]. Protect from freezing.
- Do not use the product after the expiry date marked on the packaging.

Other Questions? Where can I get more information?

Phone: 1-866-735-4137

P56836-0

PRINCIPAL DISPLAY PANEL - 45g Carton (Tube)

DIFFERIN® GEL

**ADAPALENE GEL 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 1.6 OZ (45 g)

Distributed by:

Galderma Laboratories, L.P.

Fort Worth, TX 76177 USA

All trademarks are the property of their respective owners.

Made in Canada

P57217-0



PRINCIPAL DISPLAY PANEL - 45g Carton (Pump)

DIFFERIN® GEL

**ADAPALENE GEL 0.1%
ACNE TREATMENT**

Previously available only by prescription

FDA approved

Dermatologist Developed

Once Daily Topical Retinoid*

* Read consumer information leaflet before use

Easy pump!

NET WT 1.6 OZ (45 g)

Distributed by:

Galderma Laboratories, L.P.

Fort Worth, TX 76177 USA

All trademarks are the property of their respective owners.

Made in Canada

www.differin.com

P56853-0

For position only

Unvarnish Area

DIFFERIN[®] GEL

Unvarnish Area

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

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



ACTUAL SIZE

DIFFERIN[®] GEL

ADAPALENE GEL 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 1.6 oz (45 g)

Easy pump!

Oil Free

Fragrance Free

Dermatologist developed and tested

GALDERMA

Distributed by:
Galderma Laboratories, L.P.,
Fort Worth, TX 76177 USA

All trademarks are the property of their respective owners.

Made in Canada

www.differin.com

NDC: 0299-4910-40



Drug Facts

Active ingredient	Purpose
Adapalene 0.1% retinoid*	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 use 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 nose 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

carboxer 940, edamate disodium, methylparaben, polyoxamer 182, propylene glycol, purified water and sodium hydroxide. May contain hydrochloric acid to adjust pH.

Questions? 1-800-733-4137

Unvarnish Area

LOT: _____

EXP: _____

Non-Varnished area

Unvarnish Area

For position only

adapalene gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0299-4910
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)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0299-4910-45	1 in 1 CARTON	07/08/2016	
1		45 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:0299-4910-15	1 in 1 CARTON	07/08/2016	
2		15 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:0299-4910-00	1 in 1 BLISTER PACK	07/08/2016	
3		2 g in 1 TUBE; Type 0: Not a Combination Product		
4	NDC:0299-4910-10	1 in 1 CARTON	01/01/2020	
4		15 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		
5	NDC:0299-4910-40	1 in 1 CARTON	01/01/2020	
5		45 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

NDA	NDA020380	07/08/2016	
-----	-----------	------------	--

Labeler - Galderma Laboratories, L.P. (047350186)

Establishment

Name	Address	ID/FEI	Business Operations
G Production Inc.		251676961	MANUFACTURE(0299-4910)

Revised: 12/2022

Galderma Laboratories, L.P.