

ADAPALENE- adapalene gel
YYBA Corp

GLEN MARK ADAPALENE 73581-216

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

Pregnancy/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 become 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 result
- avoid product contact 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 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 become 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 (1-800-222-1222) 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° to 77°F
- protect from freezing

Inactive ingredients

carbomer homopolymer typeC, edetate disodium, methylparaben, poloxamer 182, propylene glycol, purified water. May contain hydrochloric acid and/or sodium hydroxide to adjust pH.

Questions or comments?

Call **1-877-753-3935**

Monday-Friday 9AM-5PM EST

Principal Display Panel

†Compare to the active ingredient in Differin® Gel
Adapalene Gel USP 0.1%
Acne Treatment
Previously available only by prescription

Once daily topical retinoid*
Oil free
Fragrance free
Dermatologist developed and tested
NET WT OZ (g)

***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.

†This product is not manufactured or distributed by Galderma Laboratories, L.P. distributor of Differin® Gel.

DISTRIBUTED BY
Wellspring Meds.

NDC 73581-216-45

Adapalene Gel USP, 0.1%

NET WT. 1.6 OZ (45 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.
 ■ 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

Drug Facts (continued)

Inactive ingredients
 carbomer homopolymer, edetate disodium, phenoxyethanol, poloxamer 182, propylene glycol, purified water and sodium hydroxide

Questions? In the U.S., call weekdays 9 AM to 6 PM EST at 1-866-933-6337.

Wellspring
 Affordable Trusted Relief
 866-933-6337
 Armonk, NY 10952 U.S.A.
 wellspringmeds.com
 Product of India

ONCE DAILY TOPICAL RETINOID*

Previously available only by prescription

FDA approved

Dermatologist developed

*Read consumer information leaflet before use

PARABEN FREE

OIL FREE

FRAGRANCE FREE

DERMATOLOGISTS DEVELOPED

FDA Approved

PARABEN FREE

NET WT. 1.6 OZ (45 g)

ADAPALENE GEL

USP, 0.1%

ACNE TREATMENT

Once Daily Topical Retinoid*

welmate®

ADAPALENE

adapalene gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73581-216
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
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLOXAMER 182 (UNII: JX0HIX6OAG)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73581-216-45	1 in 1 CARTON	01/01/2026	
1		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	01/01/2026	

Labeler - YYBA Corp (006339772)