

ADAPALENE- adapalene gel
Stryke Club, Inc.

Adapalene Gel USP 0.1 percent

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

Questions or comments?

Call **415.294.0377**

Principal Display Panel

ADAPALENE GEL USP, 0.1%

FDA-APPROVED | ONCE DAILY

TOPICAL RETINOID*

DERMATOLOGIST DEVELOPED

Previously available only by prescription

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

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

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

Fragrance free and oil free

NET WT OZ (g)

TAMPER EVIDENT: DO NOT USE IF SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

DISTRIBUTED BY:

Stryke Club, Inc.

Los Angeles, CA 90069

WWW.STRYKECLUB.COM

Product Label

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 breast-feeding, ask a doctor before use.

When using this product
Avoid 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 in overall product contact with eyes, lips, and mouth. If contact occurs, immediately flush the area with water.
Do not touch hands after use

Stop use and ask a doctor if
you become pregnant, or are planning to become pregnant while using the product

if you have symptoms of an allergic reaction (such as itching, rash, hives, swelling of the lips, eyelids, and throbbing of throat)

if irritation becomes severe
if 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.

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Other information
Store at room temperature 68° to 77°F
Protect from freezing

Inactive ingredients carboxer homopolymer, edetate disodium, methylparaben, polyoxamer 182, propylene glycol, purified water, sodium hydroxide

Questions or comments?
Call 418.284.6877

ONE TUBE INSIDE

NDC 82034-888-05

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

FDA-APPROVED | ONCE DAILY TOPICAL RETINOID*

DERMATOLOGIST DEVELOPED

Previously available only by prescription

STRYKE CLUB
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STRYKE CLUB
STRYKE CLUB

*Read consumer information leaflet before use

ADAPALENE GEL
USP, 0.1%
ACNE TREATMENT

NET WT 0.5 OZ (15 g)



DERMATOLOGIST DEVELOPED AND TESTED



Fragrance free and oil free



KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

TAMPER EVIDENT: DO NOT USE IF SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

DISTRIBUTED BY:
Stryke Club, Inc.
Los Angeles, CA 90088

WWW.STRYKECLUB.COM



PLD-A570A FC007822

Lot No.:
Exp. Date:

STRYKE CLUB Adapalene Gel

ADAPALENE

adapalene gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82034-888
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:82034-888-05	1 in 1 CARTON	11/12/2021	
1		15 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	11/12/2021	

Labeler - Stryke Club, Inc. (117541253)

Revised: 11/2021

Stryke Club, Inc.