## ADAPALENE- adapalene gel Stryke Club, Inc.

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### Adapalene Gel USP 0 1 percent DELISTED

## **Active ingredient**

Agapalene 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
  - o 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 month. 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 in 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 rooms temperature 68° to 77°F
- protect from freezing

# Inactive ingredients

carbomer homopolymer, edetate disodium, methylparabem, 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.

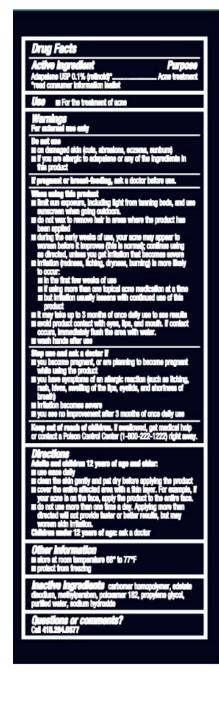
**DISTRIBUTED BY:** 

Stryke Club, Inc.

Los Angeles, CA 90069

WWW.STRYKECLUB.COM

# **Product Label**



#### ONE TUBE INSIDE

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

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ACTUAL SIZE

NDC 82034-888-05

FDA-APPROVED | ONCE DAILY TOPICAL RETINOID\*

DERMATOLOGIST DEVELOPED

Previously available only by prescription

# CTRYKE CLUB STRYKE CLUB SIKYKE GLUB

\*Read consumer information leadet before use

ADAPALENE GEL USP, 0.1% acne treatment

NET WT 0.5 0Z (15 g)

DERMATOLOGIST DEVELOPED AND TESTED



Fragrance free and oil free

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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 90069

OWW.STRYKECLUB.COM



Lot No.:

Lot No.: Exp. Date:

#### STRYKE CLUB Adapalene Gel

#### **ADAPALENE**

adapalene gel

# **Product Information**

Product TypeHUMAN OTC DRUGItem Code (Source)NDC:82034-888Route of AdministrationTOPICAL

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			
NDC:82034-888- 05	1 in 1 CARTON	11/12/2021	12/31/2024			
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	12/31/2024		

# Labeler - Stryke Club, Inc. (117541253)

Revised: 10/2023 Stryke Club, Inc.