

ADAPALENE- adapalene gel
Taro Pharmaceuticals U.S.A., Inc.

Adapalene

Drug Facts

Active ingredient

Adapalene USP, 0.1% (retinoid)¹

¹ 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

- **TAMPER EVIDENT: DO NOT USE IF THE SEAL ON THE TUBE IS PUNCTURED OR NOT VISIBLE.**
- **store at 20° to 25°C (68° to 77°F)** [see USP Controlled Room Temperature].
- protect from freezing

Inactive ingredients

carbomer homopolymer type C, edetate disodium, phenoxyethanol, poloxamer 182, propylene glycol, purified water, sodium hydroxide.

Questions?

1-866-923-4914

Distributed by:

Taro Pharmaceuticals U.S.A., Inc.

Hawthorne, NY 10532

PRINCIPAL DISPLAY PANEL - 15 g Tube Carton

Compare to the
active ingredient
in Differin® Gel†

NDC 51672-2150-1

Adapalene
Gel USP, 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 0.5 OZ (15 g)



ADAPALENE

adapalene gel

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:51672-2150

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)	
phenoxyethanol (UNII: HIE492ZZ3T)	
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:51672-2150-1	1 in 1 CARTON	01/14/2022	
1		15 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:51672-2150-6	1 in 1 CARTON	01/14/2022	
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	ANDA215940	01/14/2022	

Labeler - Taro Pharmaceuticals U.S.A., Inc. (145186370)

Establishment

Name	Address	ID/FEI	Business Operations
Taro Pharmaceuticals Inc.		206263295	MANUFACTURE(51672-2150)

Revised: 7/2023

Taro Pharmaceuticals U.S.A., Inc.