

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

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**Adapalene**

***Drug Facts***

**Active ingredient**

Adapalene USP, 0.1% (retinoid)<sup>1</sup>

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<sup>1</sup> 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.