

**ADAPALENE- adapalene gel**  
**YYBA CORP**

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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**

- **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, methylparaben, poloxamer 182, propylene glycol, purified water, sodium hydroxide.

### **Questions?**

**1-866-923-4914**

Distributed by:

Wellspring

Airmont, NY 10952, U.S.A.

### **PRINCIPAL DISPLAY PANEL - 45 g Tube Carton**

welmate

Compare to the  
active ingredient  
in Differin® Gel†

Adapalene Gel  
USP, 0.1%

Acne Treatment

ONCE DAILY TOPICAL RETINOID\*

PREVIOUSLY AVAILABLE  
ONLY BY PRESCRIPTION

DERMATOLOGIST  
DEVELOPED

FDA APPROVED

\* Read consumer information leaflet before use

NET WT 45 g (1.6 oz)



NO VARNISH/ NO AQ  
NO COPY / NO COLOR  
THIS FLAP FOR LOT #  
AND EXP DATE PRINT

1325  
B293.0  
19.166

5242629  
0023  
51

**Drug Facts** (continued)

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- protect from freezing

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**Questions?** 1-866-923-4914

\*All trademarks are property of their respective owners. This product is not affiliated with the makers/owners of Differin® Gel.

Distributed by:  
Wellspring  
Airmont, NY 10952, U.S.A.

Made in Canada



Why pay more?  
wellspringmeds.com  
866-933-6337



Compare to the active ingredient in Differin® Gel†

**Adapalene Gel  
USP, 0.1%**

**Acne Treatment**

ONCE DAILY TOPICAL RETINOID\*

PREVIOUSLY AVAILABLE ONLY BY PRESCRIPTION

DERMATOLOGIST DEVELOPED

FDA APPROVED

\*Read consumer information leaflet before use

NET WT 45 g (1.6 oz)

OIL FREE

FRAGRANCE FREE

DERMATOLOGIST DEVELOPED AND TESTED

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

\*Read carton and enclosed consumer information leaflet before using this product. Keep this carton and consumer information leaflet. They contain important information.

0.125

**Drug Facts**

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\*Read consumer information leaflet

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**Adapalene Gel  
USP, 0.1%  
Acne Treatment**





# ADAPALENE

adapalene gel

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:73581-214
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>Adapalene</b> (UNII: 1L4806J2QF) (Adapalene - UNII:1L4806J2QF)	Adapalene	1 mg in 1 g

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>Carbomer Homopolymer Type C (Allyl Pentaerythritol Crosslinked)</b> (UNII: 4Q93RCW27E)	
<b>Edetate Disodium</b> (UNII: 7FLD91C86K)	
<b>Methylparaben</b> (UNII: A218C7HI9T)	
<b>Poloxamer 182</b> (UNII: JX0HIX6OAG)	
<b>Propylene Glycol</b> (UNII: 6DC9Q167V3)	
<b>Water</b> (UNII: 059QF0KO0R)	
<b>Sodium Hydroxide</b> (UNII: 55X04QC32I)	

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:73581-214-06	1 in 1 CARTON	10/15/2023	
1		45 g in 1 TUBE; Type 0: Not a Combination Product		

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ANDA	ANDA215940	10/15/2023	

**Labeler** - YYBA CORP (006339772)

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

## Establishment

Name	Address	ID/FEI	Business Operations
Taro Pharmaceuticals Inc.		206263295	MANUFACTURE(73581-214)

Revised: 9/2023

YYBA CORP