ADAPALENE- adapalene gel RITE AID

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
- o 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: RITE AID, 200 NEWBERRY COMMONS ETTERS, PA 17319

PRINCIPAL DISPLAY PANEL - 15 g Tube Carton

NDC 11822-0062-1

ADAPALENE GEL USP, 0.1%

ACNE TREATMENT

PREVIOUSLY AVAILABLE
ONLY BY PRESCRIPTION
DERMATOLOGIST DEVELOPED

FDA APPROVED

ONCE DAILY TOPICAL RETINOID*

RYSHI ™

COMPARE TO THE ACTIVE INGREDIENT IN DIFFERIN ®GEL ‡

* Read consumer information leaflet before use

NET WT 0.5 OZ (15 g)



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Ryshi™, Let The Real You Shine Through.

First FDA-approved over-the-counter topical retinoid* for acne treatment. OIL FREE FRAGRANCE FREE PARABEN FREE

PARABEN FREE
DERMATOLOGIST
DEVELOPED AND TESTED
'READ CARTON AND ENCLOSED
CONSUMER INFORMATION
LEAFLET BEFORE USING THIS
PRODUCT. KEEP THIS CARTON
AND CONSUMER INFORMATION
LEAFLET. THEY CONTAIN
IMPORTANT INFORMATION.
'ALL TRADEMARKS ARE PROPERTY
OF THEIR RESPECTIVE OWNERS.
THIS PRODUCT IS NOT AFFILIATED
WITH THE MAKERS/OWNERS OF
DIFFERINT GEL.
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NDC 11822-0062-1



ADAPALENE GEL USP. 0.1%

ACNE TREATMENT

PREVIOUSLY AVAILABLE ONLY BY PRESCRIPTION DERMATOLOGIST DEVELOPED

FDA APPROVED

ONCE DAILY TOPICAL RETINOID*

RYSHI

COMPARE TO THE ACTIVE INGREDIENT IN DIFFERIN® GEL*

* Read consumer information leaflet before use

NET WT 0.5 OZ (15 g)

Drug Facts

Active ingredient Purpose

Adapalene USP, 0.1% Acne treatment (retinoid)*____ *read consumer information leaflet

. For the treatment of acne

Warnings For external use only

Do not use

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If pregnant or breast-feeding, ask a doctor before use.

- When using this product

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- do not wax to remove hair in areas
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Drug Facts (continued)

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Other information

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- Controlled Room Temperature].
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Inactive ingredients

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

Questions? 1-866-923-4914



ADAPALENE **GEL USP, 0.1%**

ACNE TREATMENT



ADAPALENE

adapalene gel

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:11822-0062

Route of Administration

Active Ingredient/Active Moiety

TOPICAL

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	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:11822- 0062-1	1 in 1 CARTON	04/15/2024			
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	ANDA215940	04/15/2024		

Labeler - RITE AID (014578892)

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

Establishment						
Name	Address	ID/FEI	Business Operations			
Taro Pharmaceuticals Inc.		206263295	manufacture(11822-0062)			

Revised: 4/2024 RITE AID