

ADAPALENE- adapalene gel
RUGBY LABORATORIES, 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 (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 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:

RUGBY® LABORATORIES

Indianapolis, IN 46268

PRINCIPAL DISPLAY PANEL - 45 g Tube carton

19.166
B293.0
T325

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

5249687
0424
56

Drug Facts (continued)

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, odelate disodium, phenoxylethanol, poloxamer 182, propylene glycol, purified water, sodium hydroxide.

Questions? 1-888-523-4914

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

Distributed by:
RUGBY® LABORATORIES
Indianapolis, IN 46268
(800) 616-2471
www.majorpharmaceuticals.com
Made in Canada



NDC 0536-1412-26
Compare to the active ingredient in Differin® Gel!

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

- Oil free
- Fragrance free
- Paraben 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.

NET WT 1.6 OZ (45 g)

Note: UPC Location determined by customer design team. Recommend to place at the same location as previous version.

Bleed = 0.125"
Safety Area = 0.125" ■

Drug Facts

Active Ingredient Adapalene USP, 0.1% (retinoid)*
Purpose Acne treatment
*read consumer information leaflet

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 (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 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



NDC 0536-1412-26
Compare to the active ingredient in Differin® Gel!

Adapalene Gel USP, 0.1%

Acne Treatment



NDC 0536-1412-26

Compare to the
active ingredient
in Differin[®] Gel[†]

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 1.6 OZ (45 g)

ADAPALENE

adapalene gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0536-1412
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:0536-1412-	1 is 1 CARTON	02/20/2024	

1	20	1 in 1 CARTON	02/20/2024
1		15 g in 1 TUBE; Type 0: Not a Combination Product	
2	NDC:0536-1412-26	1 in 1 CARTON	02/20/2024
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	02/20/2024	

Labeler - RUGBY LABORATORIES, INC. (079246066)

Establishment

Name	Address	ID/FEI	Business Operations
Taro Pharmaceuticals Inc.		206263295	manufacture(0536-1412)

Revised: 4/2024

RUGBY LABORATORIES, INC.