

**ADAPALENE- adapalene gel**  
**RUGBY LABORATORIES, 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 (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 VARNISH/ NO AQ  
NO COPY / NO COLOR  
THIS FLAP FOR LOT #  
AND EXP DATE PRINT

5249687  
0424  
56

**Drug Facts** (continued)

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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

NET WT 1.6 OZ (45 g)

- 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.

## Drug Facts

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

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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" ■



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Compare to the active ingredient in Differin® Gel!

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Acne Treatment



NDC 0536-1412-26

Compare to the  
active ingredient  
in Differin<sup>®</sup> Gel<sup>†</sup>

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Gel USP, 0.1%  
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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

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0536-1412
<b>Route of Administration</b>	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
Sun Pharma Canada Inc.		243339023	manufacture(0536-1412)

Revised: 7/2025

RUGBY LABORATORIES, INC.