

**PANOXYL- adapalene gel**  
**CROWN LABORATORIES**

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**PanOxyl**®

**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?**

**1-833-279-6522**

Distributed by:  
Crown Laboratories, Inc.  
Johnson City, TN 37604

**PRINCIPAL DISPLAY PANEL - 15 g Tube Carton**



NDC 0316-0143-15

PanOxyl®

ADAPALENE GEL  
USP, 0.1%

<b>PANOXYL</b>			
adapalene gel			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0316-0143
<b>Route of Administration</b>	TOPICAL		
<b>Active Ingredient/Active Moiety</b>			
	<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
	ADAPALENE (UNII: 1L4806J2QF) (ADAPALENE - UNII:1L4806J2QF)	ADAPALENE	1 mg in 1 g

## Inactive Ingredients

Ingredient Name	Strength
<b>CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED)</b> (UNII: 4Q93RCW27E)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>POLOXAMER 182</b> (UNII: JX0HIX6OAG)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0316-0143-15	1 in 1 CARTON	02/06/2023	
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	02/06/2023	

**Labeler** - CROWN LABORATORIES (079035945)

## Establishment

Name	Address	ID/FEI	Business Operations
Taro Pharmaceuticals Inc.		206263295	manufacture(0316-0143)

Revised: 8/2024

CROWN LABORATORIES