

**ADAPALENE- adapalene gel**  
**GLENMARK THERAPEUTICS INC., USA**

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**Drug Facts**

**Active ingredient**

Adapalene, USP 0.1% (retinoid)\*

\*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 breastfeeding**, 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:
- 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 room temperature 68°F to 77°F
- protect from freezing

### **Inactive Ingredients**

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

### **Questions or comments?**

**1 (888) 721-7115**

### **Patient Leaflet**

**ADAPALENE GEL USP, 0.1%**

**ACNE TREATMENT**

### **Frequently Asked Questions**

#### **What is adapalene gel 0.1% and what is it used for?**

- Adapalene gel 0.1% is a topical retinoid medication used for the treatment of acne in people age 12 years and older.

- Use only one time a day.

## **What should I know before using the product?**

- **If pregnant or breastfeeding**, ask a doctor before use.
- Some other retinoid drugs have been shown to cause birth defects. There is no specific evidence that adapalene gel 0.1% causes birth defects in humans when used topically as directed.
- **Do not use** adapalene gel 0.1% if you are allergic to adapalene or any of the ingredients in this product.
- **Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

## **How often do I apply the product?**

- Apply this product **only one time a day** and try to apply the product at the same time each day.

## **How do I apply the product?**

- Gently clean the affected areas using a mild (non-irritating) cleanser and pat dry.
- Apply adapalene gel 0.1% as a thin layer to the affected areas of the skin **only one time a day**. For example, if you get acne on the face, clean, dry and apply the product to the entire face. Adapalene gel 0.1% is **not** a spot treatment and should not be used to treat a single pimple.
- Avoid product contact with eyes, lips and mouth. **If contact occurs, immediately flush the area with water.**
- Do not apply product to damaged skin (cuts, abrasions, eczema, or sunburn).
- Wash hands after use.

## **How long will it take for adapalene gel 0.1% to work?**

- It may take up to 3 months of daily use for results to appear.
- 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.

## **What do I do if I need to be in the sun?**

- When possible, limit sun exposure, including light from tanning beds.
- When going outdoors, use a sunscreen as labeled. Your skin may be more sensitive while using adapalene gel 0.1%. If you use this product during the day, allow it to dry before applying sunscreen.

## **Can I use a moisturizer if my skin is dry?**

- Yes, use of a moisturizer may help decrease dryness and other signs of irritation. Avoid products containing alpha hydroxy or glycolic acids which may worsen irritation.

## **When is my skin most likely to become irritated? And what do I do?**

- Irritation (redness, itching, dryness, burning) is more likely to occur:

- In the first few weeks of use.
- if using abrasive skin cleansers, products with drying effects or more than one topical acne medication at a time. You may want to delay starting adapalene gel 0.1% until any irritation from using the other product(s) has gone away.
- Moisturizers may be used.
- Irritation usually lessens after 4 weeks of continued use.

### **What do I do if my skin becomes severely irritated?**

- If irritation becomes severe (overly bothersome), stop use and ask a doctor before using the product again.

### **Can I remove unwanted facial hair by waxing while using this product?**

- Do not use wax to remove hair in areas where the product has been applied because it may worsen skin irritation.

### **What ingredients are used in adapalene gel 0.1%?**

- Adapalene gel 0.1% contains:

The active ingredient is adapalene 0.1%. The other ingredients are: carbomer homopolymer, edetate disodium, phenoxyethanol, poloxamer 182, propylene glycol, purified water and sodium hydroxide.

### **How should I store this product?**

- Adapalene gel 0.1% should be stored at room temperature [68°F to 77°F]. Protect from freezing.
- Do not use the product after the expiry date marked on the packaging.

### **Other Questions? Where can I get more information?**

**Phone: 1 (888) 721-7115**

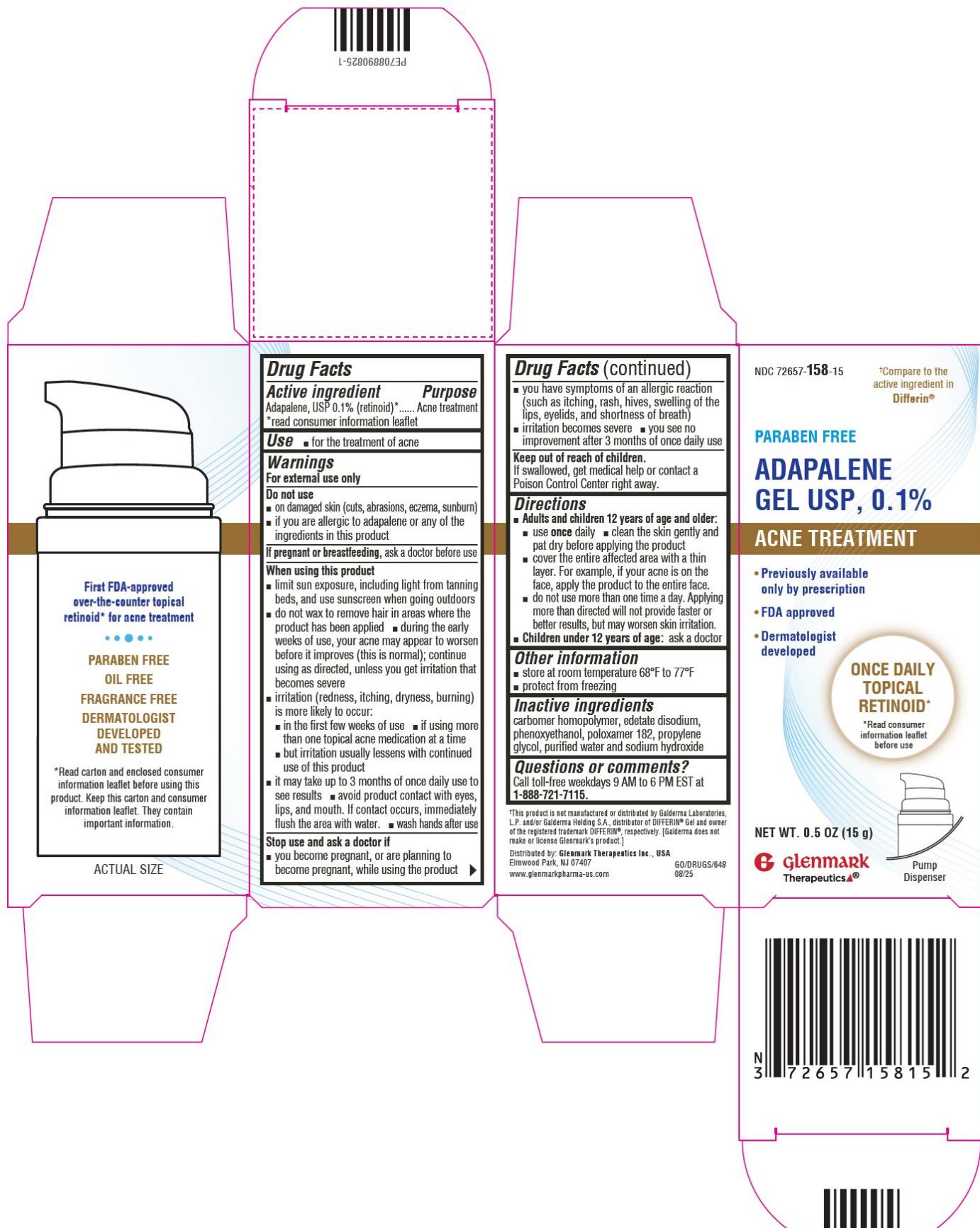
**09/25**

### **Package/Label Principal Display Panel**

**NDC 72657-158-15**

**Adapalene Gel USP, 0.1%**

**NET WT. 0.5 OZ (15 g)**

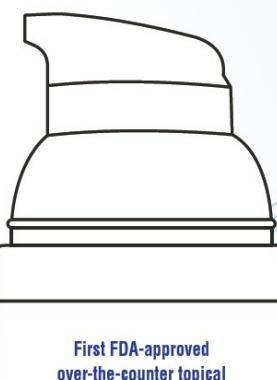


## Package/Label Principal Display Panel

**NDC 72657-158-45**

**Adapalene Gel USP, 0.1%**

**NET WT. 1.6 OZ (45 g)**



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

• • • •

**PARABEN FREE**  
**OIL FREE**  
**FRAGRANCE 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.

ACTUAL SIZE

**Drug Facts**

<b>Active ingredient</b>	<b>Purpose</b>
Adapalene, USP 0.1% (retinoid)*	Acne treatment

\*read consumer information leaflet

**Use**

- for the treatment of acne

**Warnings**

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**Drug Facts (continued)**

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ask a doctor

**Other information**

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**Inactive ingredients**

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

**Questions or comments?**  
Call toll-free weekdays 9 AM to 6 PM EST at 1-888-721-7115.

NDC 72657-158-45

\*Compare to the active ingredient in Differin®

**PARABEN FREE**

# 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)

**glenmark**  
Therapeutics®

Pump Dispenser

N 3 7 2 6 5 7 1 5 8 4 5 9





# ADAPALENE

adapalene gel

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72657-158
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)	
EDETA DISODIUM (UNII: 7FLD91C86K)	
POLOXAMER 182 (UNII: JX0HIX6OAG)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72657-158-15	1 in 1 CARTON	03/14/2025	
1		15 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		
2	NDC:72657-158-45	1 in 1 CARTON	03/14/2025	
2		45 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091314	03/10/2023	

**Labeler** - GLENMARK THERAPEUTICS INC., USA (969085666)

## Establishment

Name	Address	ID/FEI	Business Operations
Glenmark Pharmaceuticals Limited		677318665	MANUFACTURE(72657-158) , ANALYSIS(72657-158)

Revised: 1/2026

GLENMARK THERAPEUTICS INC., USA