

**BENZOYL PEROXIDE- benzoyl peroxide gel**  
**Padagis Israel Pharmaceuticals Ltd**

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**Benzoyl Peroxide 2.5% Drug Facts**

**Active ingredient**

Benzoyl peroxide 2.5%

**Purpose**

Acne treatment

**Use**

for the treatment of acne

**Warnings**

**For external use only**

**Do not use**

if you

- have very sensitive skin
- are sensitive to benzoyl peroxide

**When using this product**

- skin irritation and dryness is more likely to occur if you use another topical acne medication at the same time. If irritation occurs, only use one topical acne medication at a time.
- avoid unnecessary sun exposure and use a sunscreen
- avoid contact with the eyes, lips, and mouth
- avoid contact with hair and dyed fabrics, which may be bleached by this product
- skin irritation may occur, characterized by redness, burning, itching, peeling, or possibly swelling. Irritation may be reduced by using the product less frequently or in a lower concentration.

**Stop use and ask a doctor if**

- irritation becomes severe

**Keep out of reach of children.**

If swallowed, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

## **Directions**

- *Sensitivity Test for a New User.* Apply product sparingly to one or two small affected areas during the first 3 days. If no discomfort occurs, follow the directions stated below.
- clean the skin thoroughly before applying this product
- cover the entire affected area with a thin layer one to three times daily
- because excessive drying of the skin may occur, start with one application daily, then gradually increase to two or three times daily if needed or as directed by a doctor
- if bothersome dryness or peeling occurs, reduce application to once a day or every other day
- if going outside, apply sunscreen after using this product. If irritation or sensitivity develops, stop use of both products and ask a doctor.

## **Other information**

- store at 20°-25° (68°-77°F)

## **Inactive ingredients**

carbomer homopolymer, dimethicone, disodium lauryl sulfosuccinate, edetate disodium, glycerin, methylparaben, poloxamer 182, purified water, silicon dioxide, sodium hydroxide

## **Questions or comments?**

**1-866-634-9120**

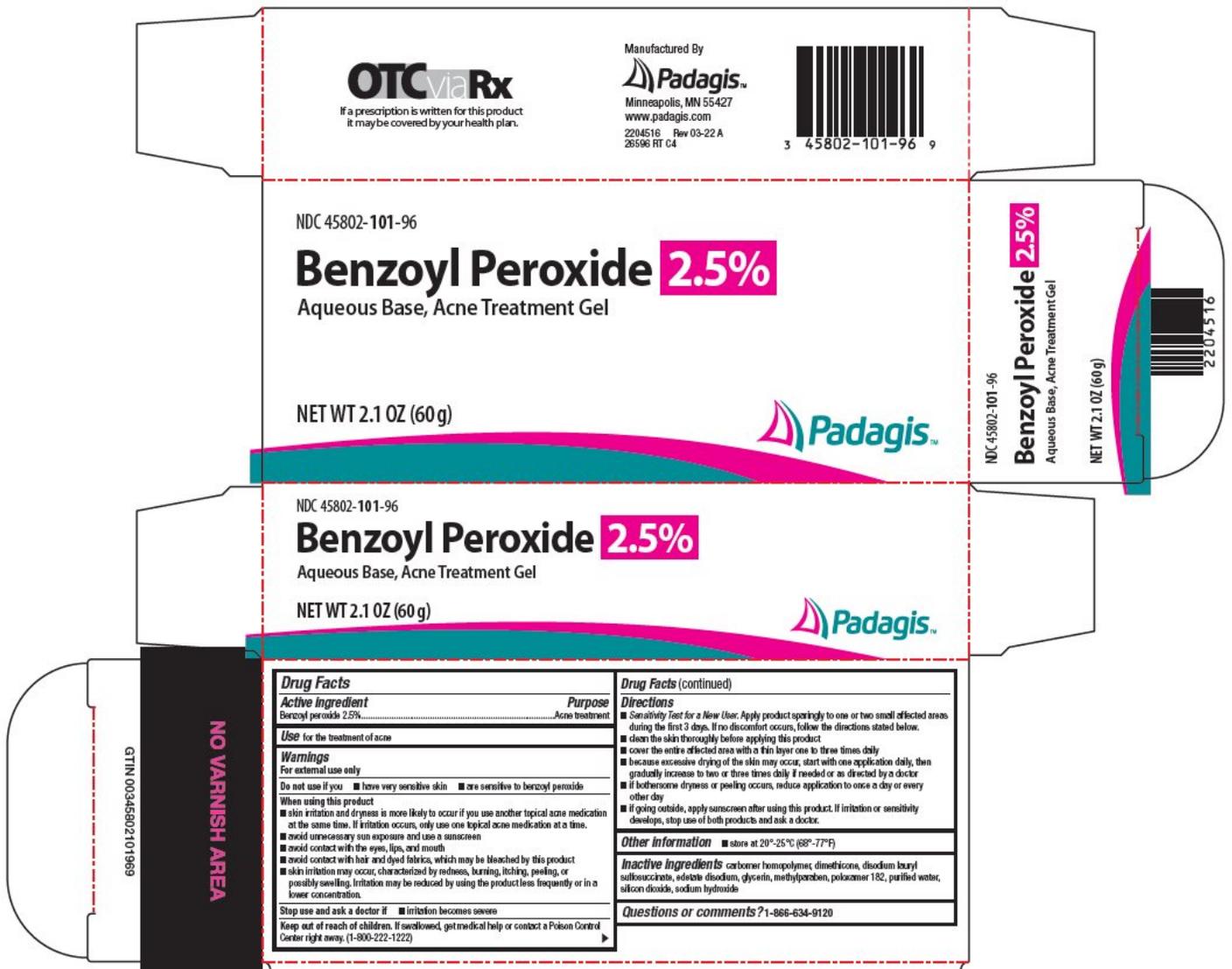
## **Package/Label Principal Display Panel**

NDC 45802-101-96

Benzoyl Peroxide 2.5%

Aqueous Base, Acne Treatment Gel

NET WT 2.1 OZ (60 g)



## BENZOYL PEROXIDE

benzoyl peroxide gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:45802-101
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>BENZOYL PEROXIDE</b> (UNII: W9WZ N9A0GM) (BENZOYL PEROXIDE - UNII:W9WZ N9A0GM)	BENZOYL PEROXIDE	2.5 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
<b>DIMETHICONE, UNSPECIFIED</b> (UNII: 92RU3N3Y1O)	

<b>DISODIUM LAURYL SULFOSUCCINATE</b> (UNII: P160Q81342)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>POLOXAMER 182</b> (UNII: JX0HIX6OAG)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	

<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:45802-101-96	1 in 1 CARTON	03/13/2012	
1		60 g in 1 TUBE; Type 0: Not a Combination Product		

<b>Marketing Information</b>			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M006	03/13/2012	

**Labeler** - Padagis Israel Pharmaceuticals Ltd (600093611)

Revised: 10/2024

Padagis Israel Pharmaceuticals Ltd