

BENZOYL PEROXIDE- benzoyl peroxide gel
Padagis Israel Pharmaceuticals Ltd

Benzoyl Peroxide 5% Drug Facts

Active ingredient

Benzoyl peroxide 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°C (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

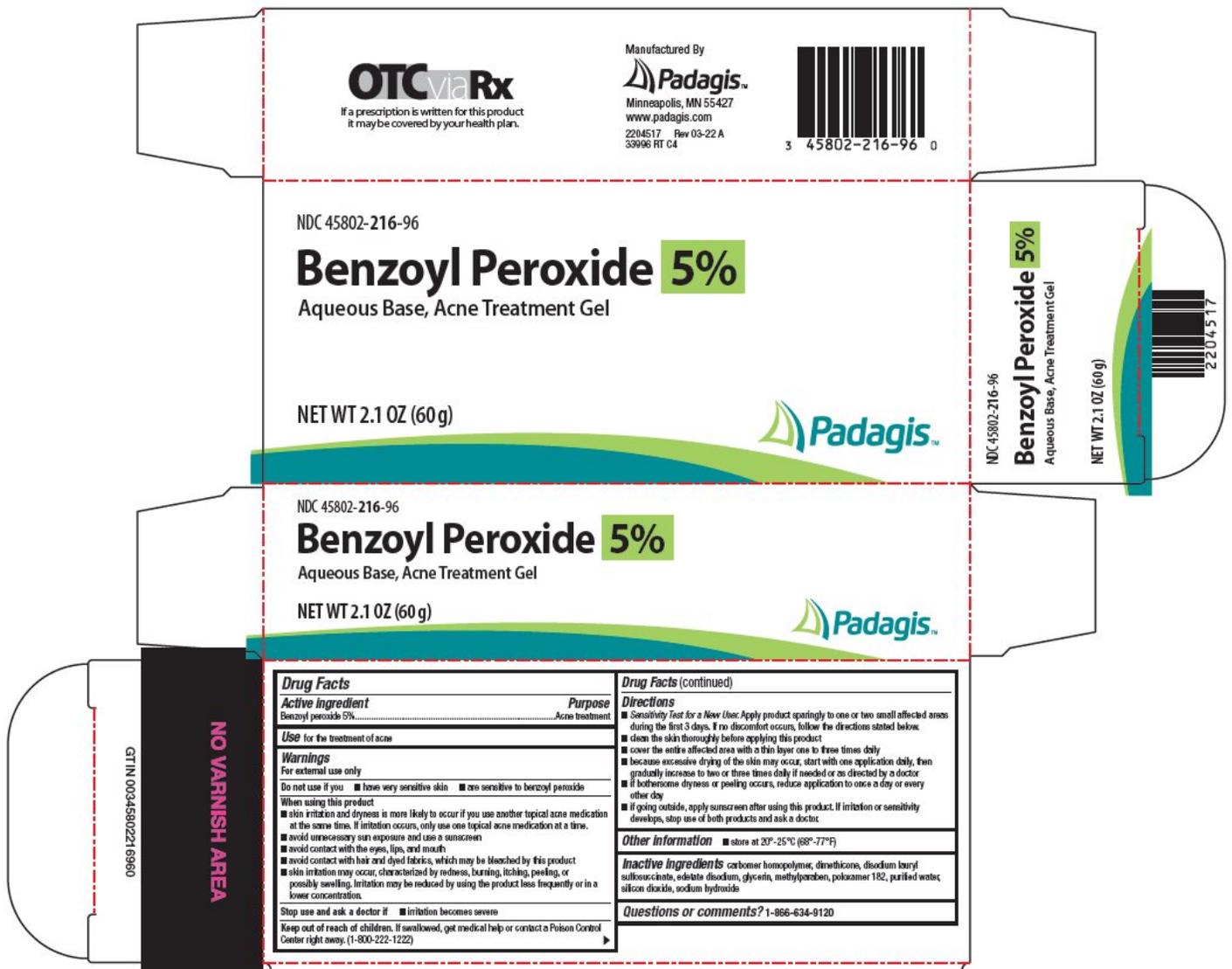
Package/Label Principal Display Panel

NDC 45802-216-96

Benzoyl Peroxide 5%

Aqueous Base, Acne Treatment Gel

NET WT 2.1 OZ (60 g)



BENZOYL PEROXIDE

benzoyl peroxide gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:45802-216
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOYL PEROXIDE (UNII: W9WZ N9A0GM) (BENZOYL PEROXIDE - UNII:W9WZ N9A0GM)	BENZOYL PEROXIDE	5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
DIMETHICONE, UNSPECIFIED (UNII: 92RU3N3Y1O)	

DISODIUM LAURYL SULFOSUCCINATE (UNII: P160Q81342)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLOXAMER 182 (UNII: JX0HIX6OAG)	
WATER (UNII: 059QF0KO0R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
CARBOMER HOMOPOLYMER TYPE B (ALLYL SUCROSE CROSSLINKED) (UNII: Z135WT9208)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:45802-216-01	1 in 1 CARTON	04/06/2012	
1		90 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:45802-216-96	1 in 1 CARTON	03/13/2012	
2		60 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
OTC Monograph Drug	M006	03/13/2012	

Labeler - Padagis Israel Pharmaceuticals Ltd (600093611)

Revised: 10/2024

Padagis Israel Pharmaceuticals Ltd