

BENZOYL PEROXIDE- benzoyl peroxide suspension
Padagis Israel Pharmaceuticals Ltd

Benzoyl Peroxide 10% Drug Facts

Active ingredient

Benzoyl peroxide 10%

Purpose

Acne medication

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

- shake well
- *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.
- wet area to be cleansed
- apply acne wash and gently massage area for 1-2 minutes
- rinse thoroughly and pat dry
- 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.

Inactive ingredients

carbomer homopolymer, citric acid*, edetate disodium, glycerin, imidurea, lauryl methacrylate/glycol dimethacrylate crosspolymer, purified water, sodium C14-16 olefin sulfonate, sodium hydroxide

*may contain this ingredient

Questions or comments?

1-800-719-9260

Package/Label Principal Display Panel

Benzoyl Peroxide 10%

Acne Medication Wash

NET WT 5 OZ (142 g)

Padagis®

NDC 45802-318-01

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10%

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Drug Facts (continued)

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1-800-719-9260

Store at 20-25°C (68-77°F)



Manufactured for Padagis®
Minneapolis, MN 55427
www.padagis.com

OTC via **Rx**

If a prescription is written for this product it may be covered by your health plan.



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EXP LOT

: 16304 RT F8

BENZOYL PEROXIDE

benzoyl peroxide suspension

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:45802-318
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	10 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
IMIDUREA (UNII: M629807ATL)	
LAURYL METHACRYLATE/GLYCOL DIMETHACRYLATE CROSSPOLYMER (UNII: EX0F4CZ66H)	
WATER (UNII: 059QF0KO0R)	
SODIUM C14-16 OLEFIN SULFONATE (UNII: O9W3D3YF5U)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:45802-318-01	142 g in 1 BOTTLE; Type 0: Not a Combination Product	02/20/2013	07/31/2026
2	NDC:45802-318-34	227 g in 1 BOTTLE; Type 0: Not a Combination Product	02/20/2013	07/31/2026

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M006	02/20/2013	07/31/2026

Labeler - Padagis Israel Pharmaceuticals Ltd (600093611)

Revised: 2/2025

Padagis Israel Pharmaceuticals Ltd