

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

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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**Perrigo 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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NET WT 5 OZ (142 g)



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1-800-719-9260

Store at 20-25°C (68-77°F)



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**OTC** via **Rx**

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



Distributed By



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## BENZOYL PEROXIDE

benzoyl peroxide suspension

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:45802-318
<b>Route of Administration</b>	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
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>IMIDUREA</b> (UNII: M629807ATL)	
<b>LAURYL METHACRYLATE/GLYCOL DIMETHACRYLATE CROSSPOLYMER</b> (UNII: EX0F4CZ66H)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM C14-16 OLEFIN SULFONATE</b> (UNII: O9W3D3YF5U)	
<b>SODIUM HYDROXIDE</b> (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	
2	NDC:45802-318-34	227 g in 1 BOTTLE; Type 0: Not a Combination Product	02/20/2013	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	02/20/2013	

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

Revised: 12/2022

Padagis Israel Pharmaceuticals Ltd