

BENZOYL PEROXIDE- benzoyl peroxide liquid
Perrigo New York Inc

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.

Perrigo Benzoyl Peroxide 5% Drug Facts

Active ingredient

Benzoyl peroxide 5%

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 5%

Acne Medication Wash

Perrigo®

NDC 45802-280-01

Benzoyl Peroxide

5%

Acne Medication Wash

NET WT 5 OZ (142g)

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Drug Facts (continued)

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Questions or comments?

1-800-719-9260

Store at 20-25°C (68-77°F).



When public and private health plans provide coverage for OTC pharmaceuticals, consumers get relief and drug formularies can reduce costs.

At Perrigo, we call it ORx



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Distributed By
Perrigo®
Allegan, MI 49010
www.perrigo.com

: 087D4 RT F3

BENZOYL PEROXIDE

benzoyl peroxide liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:45802-280
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOYL PEROXIDE (UNII: W9WZN9A0GM) (BENZOYL PEROXIDE - UNII:W9WZN9A0GM)	BENZOYL PEROXIDE	5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:45802-280-01	142 g in 1 BOTTLE		
2	NDC:45802-280-34	227 g in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	01/24/2013	

Labeler - Perrigo New York Inc (078846912)

Revised: 1/2013

Perrigo New York Inc