PHISODERM CLEAR CONFIDENCE SPOT TREATMENT- benzoyl peroxide cream
The Mentholatum Company

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.

Drug Facts

Active ingredient

Benzoyl peroxide 2.5%

Purpose

Acne treatment

Uses

treats and helps prevent 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 this product less frequently or in a lower concentration.

Stop use and ask a doctor if

irritation becomes severe

If pregnant or breast-feeding

ask a health professional before use.

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- clean skin thoroughly before applying this product
- cover entire affected area with a thin layer 1 to 3 times daily
- because excessive drying of the skin may occur, start with 1 application daily, then gradually increase to 2 or 3 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.
- *Sensitivity Test:* Apply product sparingly to a small affected area for the first 3 days. If no discomfort occurs, follow directions above.

Other information

avoid storing at temperatures above 100°F (38°C)

Inactive Ingredients

anhydrous citric acid, butylene glycol, carbomer homopolymer, diazolidinyl urea, dimethicone, dimethyl isosorbide, edetate disodium, fragrance, glycerin, iodopropynyl butylcarbamate, lauryl methacrylate/glycol dimethacrylate crosspolymer, PEG/PPG-4/12 dimethicone, portulaca oleracea extract, propylene glycol, purified water, silica, sodium citrate, sodium hydroxide, xanthan gum

Questions?

Toll free **1-877-636-2677** MON-FRI 9 AM-5 PM (EST)

Package/Label Principal Display Panel

PHISODERM CLEAR CONFIDENCE SPOT TREATMENT

benzoyl peroxide cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:10742-8293
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BENZOYL PEROXIDE (UNII: W9WZN9A0GM) (BENZOYL PEROXIDE - UNII:W9WZN9A0GM)	BENZOYL PEROXIDE	25 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	

CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
DIMETHYL ISOSORBIDE (UNII: SA6A6V432S)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
LAURYL METHACRYLATE/GLYCOL DIMETHACRYLATE CROSSPOLYMER (UNII: EX0F4CZ66H)	
PEG/PPG-4/12 DIMETHICONE (UNII: JAN3585W85)	
PURSLANE (UNII: M6S840WXG5)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10742-8293-1	1 in 1 CARTON	08/01/2013	
1		18.4 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 final	part333D	08/01/2013	

Labeler - The Mentholatum Company (002105757)

Registrant - The Mentholatum Company (002105757)

Establishment

Name	Address	ID/FEI	Business Operations
The Mentholatum Company		002105757	manufacture(10742-8293)

Revised: 2/2023 The Mentholatum Company