

BENZOYL PEROXIDE DEEP CLEANSING FOAMING WASH- benzoyl peroxide cream
AcneFree, LLC

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.

10 percent Benzoyl Peroxide

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 sunscreen
- avoid contact with the eyes, lips, and mouth
- avoid contact with hair and dyed fabrics, which may be bleached by using 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 see a doctor if skin irritation becomes severe. Keep out of reach of children.

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

Keep out of reach of children

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Directions

use every morning and evening

- apply a dime-size amount to damp skin and gently massage, avoiding the eye area
- rinse well
- use wash on entire affected area one to two times daily
- because excessive drying of the skin may occur, start with washing one daily, then gradually increase to two times daily as needed, or directed by a doctor
- if bothersome dryness or peeling occurs, reduce cleansing 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.
- may be used on chest or back

Inactive Ingredients

Water (Aqua), Glycerin, Propylene Glycol, Cocamidopropyl Hydroxysultaine, Decyl Glucoside, Sodium C14-16 Oleon Sulfonate, Xanthan Gum, Citric Acid, Potassium Hydroxide, Sodium Hyaluronate, Niacinamide, Sodium Sulfate, Avena Sativa (Oat) Kernel Extract, Sodium Lauroyl Lactylate, Glycolic Acid, Phenoxyethanol, Ceramide NP, Ceramide AP, Phytosphingosine, Cholesterol, Carbomer, Ceramide EOP

Questions or comments

1-888-768-2913

Package Label

AMBI
Printed Side
T041321A



BENZOYL PEROXIDE DEEP CLEANSING FOAMING WASH

benzoyl peroxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80861-112
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOYL PEROXIDE (UNIL-MDAZ-NAGCM) (BENZOYL PEROXIDE		0.1 %

BENZOYL PEROXIDE (UNII: W9WZ N9A0GM) (BENZOYL PEROXIDE - UNII:W9WZ N9A0GM)			BENZOYL PEROXIDE	0.1 g in 1 g
Inactive Ingredients				
Ingredient Name			Strength	
GLYCERIN (UNII: PDC6A3C0OX)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
Product Characteristics				
Color	white (cream)		Score	
Shape			Size	
Flavor			Imprint Code	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80861-112-01	1 g in 1 TUBE; Type 0: Not a Combination Product	06/21/2023	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final		M006	06/21/2023	

Labeler - AcneFree, LLC (122237140)

Establishment

Name	Address	ID/FEI	Business Operations
Universal Packaging System, INC dba Paklab		177711082	manufacture(80861-112)

Revised: 6/2023

AcneFree, LLC