SLMD AM BENZOYL PEROXIDE ACNE TREATMENT- benzoyl peroxide gel Owen Biosciences, 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.

SLMD AM Benzoyl Peroxide Acne Treatment

Active Ingredients

Benzoyl Peroxide 2.5%

Use

for the management of acne

Warnings For external use only

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

Keep out of reach of children.

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

Directions

- Clean the skin thoroughly before applying this product
- cover the entire affected area with a thin layer one to three times daily

acne treatment

topical cleanser

Inactive ingredients

Water (Aqua)

Behenoxy Dimethicone

Cyclohexasiloxane

Cyclopentasiloxane

Dimethicone

Glyceryl Stearate SE

Acetyl Carboxymethyl Cocoyl-Glycine

Lysozyme

Phenoxyethanol

Tocopheryl Acetate

Decylene Glycol

Maltodextrin

Glyceryl Stearate

PEG-100 Stearate

Caprylyl Glycol

C13-14 Isoparaffin

Laureth-7

Polyacrylamide

Sodium Carboxymethyl Betaglucan

Cocoglycerides

Glycerin

Lecithin

Palmitoyl Myristyl Serinate

Syringa Vulgaris (Lilac) Extract

Butylene Glycol

Propanediol

Mirabilis Jalapa Extract

Aloe Barbadensis Leaf Juice

Capryloyl Glycine

Polyglyceryl-10 Laurate

Tromethamine

Beta-Glucan

Myristoyl Tetrapeptide-13

Acrylates/C10-30 Alkyl Acrylate Crosspolymer

Do not use if

- have very senstive skin
- are sensitive to benzoyl peroxide

Stop us and ask a doctor if

irritation becomes severe

Acne Lotion Back.jpg

Acne Lotion Back.jpg

Drug Facts

Active ingredients Purpose

Benzoyl peroxide 2.5%.. Aone treatment gel

Use for the management of acne

Warnings

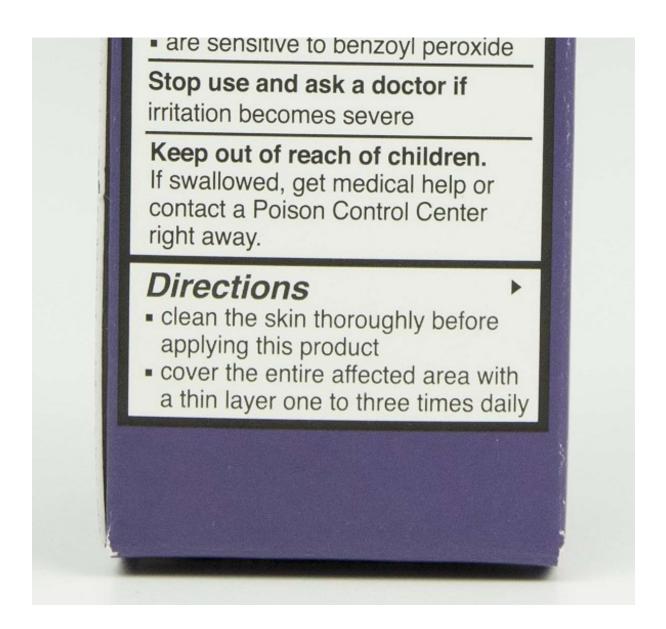
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Do not use if you

have very sensitive skin



SLMD AM BENZOYL PEROXIDE ACNE TREATMENT

benzoyl peroxide gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59958-402
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
BENZOYL PEROXIDE (UNII: W9WZ N9A0GM) (BENZ OYL PEROXIDE - UNII: W9WZ N9A0GM)	BENZOYL PEROXIDE	2.5 g in 100 g		

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	70.14 g in 100 g

DIMETHICONE (UNII: 92RU3N3Y1O)	3.8 g in 100 g	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	2 g in 100 g	

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:59958- 402-01	1 in 1 PACKAGE	03/24/2017		
1		50 g in 1 BOTTLE, PUMP; 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	03/22/2017	

Labeler - Owen Biosciences, Inc. (790003045)

Registrant - Owen Biosciences, Inc. (790003045)

Establishment					
Name	Address	ID/FEI	Business Operations		
Owen Biosciences, Inc.		790003045	manufacture(59958-402)		

Revised: 1/2023 Owen Biosciences, Inc.