

## **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.*

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### **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 sensitive 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***

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### ***Active ingredients Purpose***

Benzoyl peroxide 2.5%.. Acne treatment gel

***Use*** for the management of acne

### ***Warnings***

**For external use only.**

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**SLMD AM BENZOYL PEROXIDE ACNE TREATMENT**

benzoyl peroxide gel

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:59958-402
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>BENZOYL PEROXIDE</b> (UNII: W9WZ N9A0GM) (BENZOYL PEROXIDE - UNII:W9WZ N9A0GM)	BENZOYL PEROXIDE	2.5 g in 100 g

**Inactive Ingredients**

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	70.14 g in 100 g

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

### 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.