SLMD SILVER SULFUR ACNE CREAM- sulfur cream 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 Silver Sulfur Acne Cream -407

Active Ingredient

Sulfur 3.0%

Purpose

Acne Treatment

Use

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.
- apply only to areas with acne
- avoid contact with the eyes, lips, and mouth

Do not use on:

- broken skin
- large areas of the skin

Stop use and ask a doctor if irriatation becomes servere.

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 • because excessive drying of the skin may occur, start with one applicagtion 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
- 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 above.

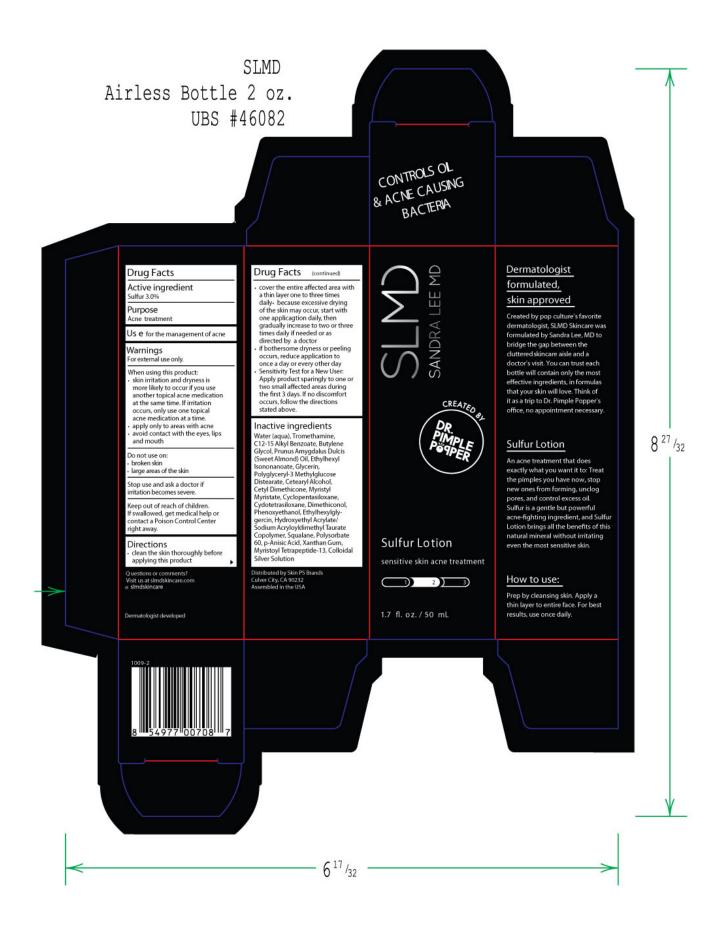
Water (agua), Tromethamine, C12-15 Alkyl Benzoate, Butylene Glycol, Prunus Amygdalus Dulcis (Sweet Almond) Oil, Ethylhexyl Isononanoate, Glycerin, Polyalyceryl-3 Methylalucose Distearate, Cetearyl Alcohol, Cetyl Dimethicone, Myristyl Myristate, Cyclopentasiloxane, Cydotetrasiloxane, Dimethiconol, Phenoxyethanol, Ethylhexylglygercin, Hydroxyethyl Acrylate/ Sodium Acryloyldimethyl Taurate Copolymer, Squalane, Polysorbate 60, p-Anisic Acid, Xanthan Gum, Myristoyl Tetrapeptide-13, Colloidal Silver Solution

Keep out of reach of children.

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

Sulfur Carton.jpg

Sulfur Carton.jpg



sulfur cream

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:59958-407

Route of Administration TOPICAL

Active Ingredient/Active Moiety

	Ingredient Name	Basis of Strength	Strength
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SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70) SULFUR 3 g in 100 g

Inactive Ingredients

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Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)	71.69 g in 100 g	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	3 g in 100 g	
ALMOND OIL (UNII: 66YXD4DKO9)	3 g in 100 g	

Packaging

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	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 (NDC:59958-407- 02	1 in 1 CARTON	08/30/2019	
	1 (NDC:59958-407- 01	50 g in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date
OTC monograph final	part333D	08/30/2019	

Labeler - Owen Biosciences Inc. (790003045)

Registrant - Owen Biosciences Inc. (790003045)

Establishment

Name	Address	ID/FEI	Business Operations
Owen Biosciences Inc.		790003045	manufacture(59958-407)

Revised: 1/2023 Owen Biosciences Inc.