SULFUR ACNE FOAMING CLEANSER- sulfur cream Acne Free, 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.

Active Ingredient

Sulfur 3.5 percent

Purpose

Acne Treatment

Warnings

For external use only

Do not use on

broken skin

large areas of skin

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

Keep out of reach of children

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

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
- may be used on chest or back

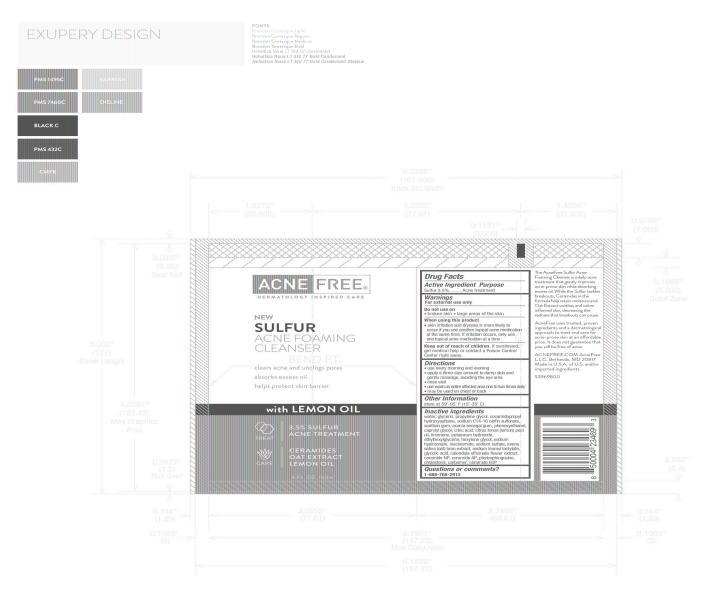
Other Information

Inactive Ingredients

water, glycerin, propylene glycol, cocamidopropyl hydroxysultaine, sodium C14-16 olefin sulfonate, xanthan gum, acacia senegal gum, phenoxyethanol, caprylyl glycol, citric acid, citrus limon (lemon) peel oil, limonene, potassium hydroxide, ethylhexylglycerin, hexylene glycol, sodium hyaluronate, niacinamide, sodium sulfate, avena sativa (oat) bran extract, sodium lauroyl lactylate, glycolic acid, calendula officinalis flower extract, ceramide NP, ceramide AP, phytosphingosine, cholesterol, carbomer, ceramide EOP

Questions or comments?

1-888-768-2913



sulfur cream

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:80861-113

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength

SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)

SULFUR

0.001 g in 1 g

Inactive Ingredients

Ingredient Name	Strenath
ingredient wante	Strellgtti

GLYCERIN (UNII: PDC6A3C0OX)

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)

Product Characteristics

Color	white (cream)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

ı					
	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
	1 NDC:80861-113-	1 g in 1 TUBE; Type 0: Not a Combination Product	06/22/2023		

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date
OTC monograph final	M006	06/22/2023	

Labeler - Acne Free, LLC (122237140)

Establishment

Establishment				
Name	Address	ID/FEI	Business Operations	
Universal Packaging Systems, INC, dba Paklab		177711082	manufacture(80861-113)	

Revised: 6/2023 Acne Free, LLC