

**DERMAHARMONY SULFUR AND SALICYLIC ACID- salicylic acid, sulfur liquid**  
**D3 Development, 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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**Dermaharmony Sulfur and Salicylic Acid Liquid Soap**

***Drug Facts***

***Active ingredient***

Salicylic Acid 2%

Sulfur 5%

***Purpose***

Dandruff / seborrheic dermatitis / psoriasis soap

***Uses***

☐Helps prevent and control recurrence of itching, flaking and irritation associated with dandruff, seborrheic dermatitis, and psoriasis

***Warnings***

**For external use only.**

**Ask a doctor before use if you have** a condition that covers a large area of the body.

**When using this product,** avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water.

**Stop use and ask a doctor if** condition worsens or does not improve after regular use as directed.

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

***Directions***

- Use on affected areas in place of your regular soap or shampoo.
- For best results use at least twice a week or as directed by a doctor.
- Work up a lather using warm water and massage into affected areas.
- Rinse.

***Other information***

- Store at 59° to 77°F (15° to 25°C)
- Lot number/expiration date are printed on bottom of this bottle.

***Inactive ingredients***

Water, Potassium Cocoate, Potassium Oleate, Potassium Oliviate, Sodium Acrylates / Beheneth-25 Methacrylate Crosspolymers, Pumice, Glycerin, Acrylates Copolymer, Citric Acid

***Questions?***

**1-800-827-3730**

[www.dermaharmony.com](http://www.dermaharmony.com)

**Distributed by:**

D3 Development, Inc., Portland, ME 04101

Made in the USA

dermaharmony

### Sulfur & Salicylic Acid SOAP

For Dandruff, Sebhorreic Dermatitis & Psoriasis

### MEDICATED NATURAL CASTILE SOAP

4 FL OZ (118 ml)

<b>Drug Facts (continued)</b>
<b>Directions</b> ■ Use on affected areas in place of your regular soap or shampoo. ■ For best results use at least twice a week or as directed by a doctor. ■ Work up a lather using warm water and massage into affected areas. ■ Rinse.
<b>Other information</b> ■ Store at 59° to 77°F (15° to 25°C) ■ Lot number/expiration date are printed on bottom of this bottle.
<b>Inactive ingredients</b> Water, Potassium Cocoate, Potassium Oleate, Potassium Oliviate, Sodium Acrylates / Beheneth-25 Methacrylate Crosspolymers, Pumice, Glycerin, Acrylates Copolymer, Citric Acid
<b>Questions?</b> 1-800-827-3730    www.dermaharmony.com
<b>Distributed by:</b> Made in the USA D3 Development, Inc., Portland, ME 04101

<b>Drug Facts</b>
<b>Active ingredient</b> <b>Purposes</b> Salicylic Acid 2% } ..... Dandruff / sebhorreic Sulfur 5%                      dermatitis / psoriasis soap
<b>Uses</b> Helps prevent and control recurrence of itching, flaking and irritation associated with dandruff, sebhorreic dermatitis, and psoriasis.
<b>Warnings</b> <b>For external use only.</b>
<b>Ask a doctor before use</b> if you have a condition that covers a large part of the body.
<b>When using this product</b> avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water.
<b>Stop use and ask a doctor</b> if condition worsens or does not improve after regular use as directed.
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

## DERMAHARMONY SULFUR AND SALICYLIC ACID

salicylic acid, sulfur liquid

Product Information			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:718 19-006
<b>Route of Administration</b>	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)		SULFUR	5 g in 100 mL
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)		SALICYLIC ACID	2 g in 100 mL

Inactive Ingredients		
Ingredient Name		Strength
ACRYLIC ACID (UNII: J94PBK7X8S)		
CARBOMER HOMO POLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: F68VH75CJC)		
CARBOMER HOMO POLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)		
PUMICE (UNII: NT5NN5KL16)		
WATER (UNII: 059QF0KO0R)		
POTASSIUM COCOATE (UNII: F8U72V8ZXP)		
GLYCERIN (UNII: PDC6A3C0OX)		
POTASSIUM OLIVATE (UNII: 3H8EO46QKE)		
POTASSIUM OLEATE (UNII: 74WHF607EU)		
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)		

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71819-006-04	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/27/2020	
2	NDC:71819-006-10	296 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/27/2020	
3	NDC:71819-006-12	355 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/27/2020	
4	NDC:71819-006-64	1893 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/27/2020	
5	NDC:71819-006-99	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/27/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358H	03/27/2020	

**Labeler** - D3 Development, Inc. (043195877)

Revised: 3/2020

D3 Development, Inc.