### DERMASOLVE MEDICATED- salicylic acid soap Fortitude Health, LLC

-----

### DermaSolve Body Wash

Salicylic Acid 3%

Psoriasis/Seborrheic Dermatitis/Dandruff

Controls the symptoms associated with Psoriasis, Seborrheic Dermatitis and/or Dandruff including itching, scaling, flaking, redness, and irritation.

### For external use only.

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

When using this product avoid contact with the 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 of this product as directed.

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

For best results use at least twice a week or as directed by a doctor.

- Use on affected areas in place of your regular soap
- Apply onto moistened skin
- Allow later to remain on skin for several minutes
- Rinse thoroughly with warm water and pat dry. For best results use at least twice a week or as directed by a doctor.
- A patch test should be done prior to use if you are concerned about any ingredients.
- This is a low foam shampoo.
- Can be used daily

Deionized Water, Sodium Laryl Ether Sulfate, Coamidopropyl Betaine, Cetyl Alcohol, Cetearyl Alcohol, Ceteareth-20, Ethylene Glycol Monostearate, Egg Powder, Aloe Barbadensis Leaf Juice, Polyquaternium-7, Citrus Paradisi (Grapefruit) Seed Oil, Propylene Glycol, Phenoxyethanol, Ethylhexylglycerin, Sodium Benzoate, Triethanolamine, Disodium EDTA.

PSORIASIS	Drug Facts		
Dandruff - Seborrheic Dermatitis	Active Ingredient         Purpose           Salicylic Acid 3%         Psoriasis/Seborrheic Dermatitis		
Medicated	Indications Controls the symptoms assoicated with Psoriasis and/or Sebhorrheic Dermatitis including ■ itching ■ scaling ■ flaking ■ redness ■ irritation		
<b>BODY WASH</b>	<i>Warnings</i> For external use only.		
Plus CONDITIONER	Ask a doctor before use if you have a condition that covers a large area of the body.		
3% SALICYLIC ACID	When using this product avoid contact with the eyes. If contact occurs, rinse eyes thoroughly with water.		
With Patented	Stop use and ask a doctor if condition worsens or does not improve after regular use of this product as directed.		
TECHNOLOGY	Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.		
<ul> <li>For use anywhere on the body</li> <li>Relieves itching &amp; irritation</li> </ul>	<b>Directions</b> For best results use at least twice a week or as directed by a doctor Use on affected areas in place of your regular soap Apply onto moistened skin Allow lather to remain on skin for several minutes Rinse thoroughly with warm water and pat dry. A patch test should be done prior to use if you are concerned abou any ingredients This is a low foam bodywash Can be used daily		
<ul> <li>For use anywhere on the body</li> <li>Relieves itching &amp; irritation</li> <li>Gently cleanses</li> <li>Immediate &amp; continuous relief</li> <li>Controls scaly build-up</li> <li>Non-greasy</li> <li>Irritation-free formula</li> <li>Helps prevent recurrence</li> <li>Doctor recommended</li> <li>Fragrance free</li> </ul>	<b>Inactive Ingredients</b> Deionized Water, Sodium Lauryl Ethyl Sulfate (SLES), Cocamidopropyl betaine, Cetyl Alcohol, Cetearyl alcohol, Ceteareth 20, Ethylene Glycol Monostearate, Egg Powder, Aloe Barbadensis Leaf Juice, Polyquaternium-7, Citrus Paradisi (Grapefruit) Seed Oil, Propylene Glycol, Phenoxyethanol, Ethylhexylglycerin, Sodium Benzoate, Triethanolamine, Disodium EDTA.		
<ul> <li>Helps prevent recurrence</li> <li>Doctor recommended</li> </ul>	Questions or Comments 1-973-396-8480		
Fragrance free	Made in USA		
Net Wt. 8oz / 226g	7 91612 10024 9 www.DERMASOLVE.com Pine Brook, NJ 07058		

# **DERMASOLVE MEDICATED**

salicylic acid soap

Product Information						
Product Type	HUMAN OTC DRUG	HUMAN OTC DRUG Item Code (Source) NDC:		NDC:84	84285-102	
Route of Administration	TOPICAL					
Active Incursions (Active Meister						
Active Ingredient/Active Moiety						
Ingredient Name Basis of Streng				ength	Strength	
SALICYLIC ACID (UNII: 0414PZ4LPZ) (SALICYLIC ACID - UNII:0414PZ4LPZ)			SALICYLIC ACID		3 g in 100 g	
Inactive Ingredients						
Ingredient Name			9	Strength		
CETEARETH-20 (UNII: YRC528SWU	Y)					

	MONOSTEARATE (UNII: TWG3GKC3M9)		
EGG (UNII: 291P45F896)			
ALOE BARBADENSIS L	EAF JUICE (UNII: ZY81Z83H0X)		
CETYL ALCOHOL (UNII:	936JST6JCN)		
COCAMIDOPROPYL BE	TAINE (UNII: 50CF3011KX)		
GRAPEFRUIT SEED OIL	. (UNII: 598D944HOL)		
SODIUM LAURETH SUL	FATE (UNII: BPV390UAP0)		
WATER (UNII: 059QF0KC	OOR)		
POLYQUATERNIUM-7 (	UNII: 0L414VCS5Y)		
PHENOXYETHANOL (UI	NII: HIE492ZZ3T)		
CETEARYL ALCOHOL	JNII: 2DMT128M1S)		
PROPYLENE GLYCOL (	JNII: 6DC9Q167V3)		
SODIUM BENZOATE (U	NII: OJ245FE5EU)		
TROLAMINE (UNII: 903k	(93S3TK)		
EDETATE DISODIUM (L	INII: 7FLD91C86K)		
Packaging			
# Item Code	Package Description	Marketing Start	Marketing End

	#	ltem Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:84285-102- 08	226 g in 1 BOTTLE; Type 0: Not a Combination Product	10/21/2024	
l					

Marketing Information				
Marketing CategoryApplication Number or Monograph Citation		Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M032	10/21/2024		
	11032	10/21/2024		

### Labeler - Fortitude Health, LLC (064309530)

## Registrant - Stream2Sea LLC (052920828)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Stream2Sea, LLC		052920828	manufacture(84285-102)	

Revised: 10/2024

Fortitude Health, LLC