

ACNE CARE LOTN- salicylic acid lotion Spa de Soleil

Acne Lotion

Active ingredient Purpose

Salicylic Acid (0.5%).....Acne Treatment

Sulfur (2.0%).....Acne Treatment

Purpose

Acne Treatment

For treatment of acne

Warnings

For external use only

Avoid contact with eyes. If contact occurs, rinse thoroughly with water.

If swallowed, get medical help or contact a Poison Control Center right away. If excessive skin irritation develops or increases, discontinue use and consult a doctor. Keep out of reach of children.

Keep out of reach of children. In case of accidental ingestion, get medical help or contact a Poison Control Center right away.

When using this product

- Skin irritation and dryness is more likely to occur if you use another topical acne medication while using this product. If irritation occurs, use only one topical acne medication at a time.

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 application 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.

Other Ingredients:

Aqua, PEG – 100 Stearate, Glyceryl Stearate, Glycerin, Stearic Acid, Cetyl Alcohol, Titanium Dioxide, Butylene Glycol, Carthamus Tinctorius (Safflower) Seed Oil, Zinc Oxide, Hydroxyethyl Cellulose, Sodium Hydroxide, Phenoxyethanol, Ethylhexylglycerin, Chloroxylenol, Tocopheryl Acetate (Vitamin E), Ascorbic Acid (Vitamin C), Malus Domestica (Apple) Fruit Cell Culture Extract, Citric Acid, Lactic Acid, Malic Acid, Gluconic Acid, Glycolic Acid, Salicylic Acid, Tartaric Acid, *CO Alcohol, *CO Glycerin, *CO Salix Alba Bark Extract, *CO Avena Sativa (Oat) Kernel Extract, *CO Hamamelis Virginiana (Witch Hazel) Bark/Leaf/Twig Extract, *CO Pogostemon Cablin Oil, *CO Melaleuca Alternifolia (Tea Tree) Leaf Oil, Disodium EDTA, Sea Salt, **Squalane, Fragrance.

Acne Lotion is formulated with Salicylic Acid to help fight acne, prevent future breakouts, and treat oily skin and blemishes. Salix Alba Bark Extract targets multiple acne symptoms, such as inflammation, irritation, and redness. Infused with Organic Fruit Extracts to prevent dryness and peeling.

Drug Facts

Active Ingredient	Purpose
Salicylic Acid 1.0%.....	Acne Treatment
Sulfur 2.0%.....	Acne Treatment

Uses For treatment of acne

Warnings For external use only. Avoid contact with eyes. If contact occurs, rinse thoroughly with water. If swallowed, get medical help or contact a Poison Control Center immediately. If excessive skin irritation develops or increases, discontinue use and consult a doctor. **Keep out of reach of children.**

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Inactive Ingredients:

Aqua, PEG-100 Stearate, Glyceryl Stearate, Glycerin, Stearic Acid, Cetyl Alcohol, Titanium Dioxide, Butylene Glycol, Carthamus Tinctorius (Safflower) Seed Oil, Hydroxyethylcellulose, Sodium Hydroxide, Phenoxyethanol, Ethylhexylglycerin, Chloroxyleneol, Tocopheryl Acetate (Vitamin E), Ascorbic Acid (Vitamin C), Zinc Oxide, *CO Glycerin, Sea Salt (Dead Sea Salt), *CO Salix Alba (Willow) Bark Extract, *CO Hamamelis Virginiana (Witch Hazel) Extract, *CO Avena Sativa (Oat) Kernel Extract, Retinyl Palmitate (Vitamin A), *CO Pogostemon Cablin Leaf Extract, *CO Melaleuca Alternifolia (Tea Tree) Leaf Oil, Disodium EDTA, Citronellol, Fragrance. *CO Certified Organic

Manufactured for:

MADE IN USA
AT1704.Ver 01



SHAKE WELL

.....
ACNE LOTION
COMBINATION-TO-OILY

4 fl. oz | 120 mL

ACNE CARE LOTN

salicylic acid lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68062-2267
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	1 mg in 100 mL
SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	2 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
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PEG-100 STEARATE (UNII: YD01N1999R)	
GLYCERYL STEARATE/PEG-100 STEARATE (UNII: RD25J5V947)	
GLYCERIN (UNII: PDC6A3C0OX)	
STEARIC ACID D7 (UNII: T3B081197X)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68062-2267-1	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/19/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M006	11/19/2023	

Labeler - Spa de Soleil (874682867)

Registrant - Spa de Soleil (874682867)

Establishment

Name	Address	ID/FEI	Business Operations
Spa de Soleil		874682867	manufacture(68062-2267)

Revised: 11/2023

Spa de Soleil