

DERMATOUCH ACNECARE MOISTURIZER- salicylic acid cream **Spa de Soleil**

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.

Dermatouch Acnecare Moisturizer

Active ingredient Purpose

Salicylic Acid (1.0%).....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, Glycerin, Caprylic/Capric Triglyceride, Cetyl Alcohol, Cetearyl Alcohol, Olea Europaea (Olive) Fruit Oil, Glyceryl Stearate SE, Carthamus Tinctorius (Safflower) Seed Oil, Cetearyl Glucoside, Xanthan Gum, Tocopheryl Acetate (Vitamin E), Disodium EDTA, Avena Sativa (Oat) Kernel Flour, Caffeine, *CO Aloe Barbadosensis Leaf Powder, Sodium Hyaluronate (Hyaluronic Acid), Ascorbic Acid (Vitamin C), Retinyl Palmitate (Vitamin A), Phenoxyethanol, Ethylhexylglycerin, Fragrance. *CO - Organic

50 ML 1.7 FL OZ	Dermatouch® ACNECARE™ Salicylic Acid & Oatmeal DAILY CONTROL FOR CLEAR SKIN MOISTURIZER	CLEAR BEAUTY	Drug Facts Active Ingredient Salicylic Acid 1.0%.....Acne Treatment Purpose Acne Treatment Uses For treatment of acne	Drug Facts (Continues) Warnings(Continued) 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(Continued) • 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 Questions? Call 1-800-266-9506 M-F, 9am-5pm EST
	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.		Directions • Clean the skin thoroughly before applying this product • Cover the entire affected area with a thin layer one to three times daily	DMTACN120-B Manufactured by Spa de Soleil, Inc. www.homespacollection.com	

DERMATOUCH ACNECARE MOISTURIZER

salicylic acid cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68062-9006
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	0.5 mg in 50 mL

Inactive Ingredients

Ingredient Name	Strength
CAPRYLIC/CAPRIC/LAURIC TRIGLYCERIDE (UNII: FJ1H6M2JG9)	
WATER (UNII: 059QF0KO0R)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERIN (UNII: PDC6A3C0OX)	
OLIVE OIL (UNII: 6UYK2W1W1E)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68062-9006-1	50 mL in 1 JAR; Type 0: Not a Combination Product	03/29/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M006	03/29/2023	

Labeler - Spa de Soleil (874682867)

Registrant - Spa de Soleil (874682867)

Establishment

Name	Address	ID/FEI	Business Operations
Spa de Soleil		874682867	manufacture(68062-9006)

Revised: 3/2023

Spa de Soleil