

## **ACNE MOISTURIZER- salicylic acid cream Spa de Soleil**

### **Acne 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 Barbadensis Leaf Powder, Sodium Hyaluronate (Hyaluronic Acid), Ascorbic Acid (Vitamin C), Retinyl Palmitate (Vitamin A), Phenoxyethanol, Ethylhexylglycerin, Fragrance. \*CO – Organic

**ACNE  
MOISTURIZER**



1.5 fl oz | 45 mL

**Drug Facts**

**Active Ingredient**  
Salicylic Acid 1.0%

**Purpose**  
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.**

DMTACN120-PL

**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**  
• Clean the skin thoroughly before applying this product. • Cover the entire affected area with a thin layer one to three times daily.

**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.

**Other Ingredients:** Aqua, Glycerin, Caprylic/Capric Triglyceride, Cetyl Alcohol, Cetearyl Alcohol, Olea Europaea (Olive) Fruit Oil, Glyceryl Stearate SE, Carbomer, Tocopherol (Sunflower) Seed Oil, Cetanoyl Glucoside, Xanthan Gum, Tocopherol Acetate (Vitamin E), Oleodan EDTA, Avena Sativa (Oat) Kernel Flour, Caffeine, \*CO Aloe Barbadensis Leaf Powder, Sodium Hyaluronate (Hyaluronic Acid), Ascorbic Acid (Vitamin C), Retinol Palmitate (Vitamin A), Phenylethyl Alcohol, Ethylhexylglycerin, Fragrance. \*CO-Certified Organic

MADE IN USA  
Manufactured for:

**ACNE MOISTURIZER**

salicylic acid cream

**Product Information**

|                                |                |                           |                |
|--------------------------------|----------------|---------------------------|----------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:68062-9907 |
| <b>Route of Administration</b> | TOPICAL        |                           |                |

**Active Ingredient/Active Moiety**

| Ingredient Name   | Basis of Strength | Strength        |
|---|-------------------|-----------------|
| <b>SALICYLIC ACID</b> (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ) | SALICYLIC ACID    | 0.5 mg in 50 mL |

**Inactive Ingredients**

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

**Packaging**

| # | Item Code        | Package Description                               | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:68062-9907-1 | 45 mL in 1 JAR; 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(68062-9907) |

Revised: 11/2023

Spa de Soleil