ACNE DRYING- salicylic acid lotion
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.

Acne Drying Lotion

Active ingredient Purpose

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

Purpose

Acne Medication

Use for the management of acne

Warnings: For external use only. Using other topical acne medications at the same time or immediately following use of this product may increase dryness or irritation of the skin. If this occurs, only one medication should be used unless directed by a doctor. Sensitivity test for new users: Apply product sparingly to one or two small affected areas during the first three days. If no discomfort occurs, follow the steps stated in directions.

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

Directions: Cleanse skin thoroughly before applying medication . Cover the entire affected area with a thin layer one to two 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: Isopropyl Alcohol, Aqua, Calamine, Aluminum Starch Octenylsuccinate, Zinc Oxide, Glycerin, Camphor, Colloidal Sulfur, *CO Glycerin, *CO Humulus Lupulus (Hops) Extract, *CO Lavandula Angustifolia (Lavender) Flower/Leaf/Stem Extract, *CO Calendula Officinalis Flower Extract, *CO Chamomilla Recutita (Matricaria) Flower Extract, *CO Citrus Limon (Lemon) Peel Extract, *CO Cucumis Sativus (Cucumber) Seed Extract, *CO Camellia Sinensis Leaf Extract, *CO Pyrus Malus (Apple) Fruit Extract, *CO Spirulina Platensis Extract.

*CO Certified Organic

DRYING LOTION

HELPS CLEAR UP ACNE BLEMISHES

shake well

Gluten-Free • Mineral-Oil-Free
Formaldehyde-Free • Non-Nano
Sulfate-Free • Lanolin-Free

1.7 fl. oz e 50 mL

Fast and effective, this spot Drying Lotion quickly gets to work on pimples and flare-ups. Specifically formulated to help reduce redness, combat inflammation, and dry up problematic whiteheads. Drying lotion effectively tackles breakouts so you can enjoy a healthy, clear complexion.

Drug Facts

Active ingredient **Purpose**
Salicylic Acid (0.5%)...Acne Medication

Use for the management of acne

When using this product avoid contact with eyes. If contact occurs, immediately flush with water.

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

Warnings: **For external use only.** Using other topical acne medications at the same time or immediately following use of this product may increase dryness or irritation of the skin. If this occurs, only one medication should be used unless directed by a doctor. **Sensitivity test for new users:** Apply product sparingly to one or two small affected areas during the first three days. If no discomfort occurs, follow the steps stated in directions.

Drug Facts *(continued)*

Directions ▪ Cleanse skin thoroughly before applying medication ▪ Cover the entire affected area with a thin layer one to two 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.

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Manufactured for :

MADE IN USA SDSDL21-PL

ACNE DRYING

salicylic acid lotion

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68062-9003
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 g in 50 mL

Inactive Ingredients

Ingredient Name	Strength
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ0O6294)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
WATER (UNII: 059QF0KO0R)	

Packaging

			Marketing Start	Marketing End

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68062-9003-1	50 mL in 1 TUBE; Type 0: Not a Combination Product	09/15/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	09/15/2021	

Labeler - Spa de Soleil (874682867)

Registrant - Spa de Soleil (874682867)

Establishment

Name	Address	ID/FEI	Business Operations
Spa de Soleil		874682867	manufacture(68062-9003)

Revised: 9/2021 Spa de Soleil