

ACNE TREATMENT PADS- 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 Treatment Pads

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 the skin thoroughly before applying medication. Use the pad to wipe the entire affected area one to three times daily. . Repeat with a clean pad as necessary to remove remaining traces of dirt. . 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, Sodium Methyl 2-Sulfolaurate, Disodium 2-Sulfolaurate, Sodium Xylene Sulfonate, Menthol, *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, Disodium EDTA, Simethicone, Ethylhexylglycerin, Phenoxyethanol, Fragrance.

*CO Certified Organic

60 pre-moistened Acne Pads are formulated with 0.5% salicylic acid to help blast blemishes, stop future flare-ups and breakouts, and work to achieve smooth, clear skin.

Drug Facts		Drug Facts <i>(continued)</i>	
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Use for the management of acne		Other ingredients: Aqua, Sodium Methyl 2-Sulfolaurate, Disodium 2-Sulfolaurate, Sodium Xylene Sulfonate, Menthol, *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, Disodium EDTA, Simethicone, Ethylhexylglycerin, Phenoxyethanol, Fragrance. *CO Certified Organic	
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.			
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Manufactured for :		ACP21-PL	MADE IN USA



ACNE TREATMENT PADS

salicylic acid lotion

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68062-9004	
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	
GLYCERIN (UNII: PDC6A3C0OX)				
MENTHOL (UNII: L7T10EIP3A)				
WATER (UNII: 059QF0KO0R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68062-9004-1	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(68062-9004)

Revised: 9/2021

Spa de Soleil