CLARITY CLEAR SKIN ESSENTIALS ACNE SPOT TREATMENT- salicylic acid cream Melaleuca Inc.

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.

Clarity Clear Skin Essentials Acne Spot Treatment

Active Ingredient

Salicylic acid 2.0%

Purpose

Acne Treatment

Use for the treatment and management of acne

Warnings

For external use only. Do not get into eyes. If contact occurs, rinse eyes thoroughly with water.

When using this product skin irritation and dryness is more likely top occur if you use another topical acne medication at the same time. If this occurs, only one acne medication should be used unless otherwise directed by a doctor.

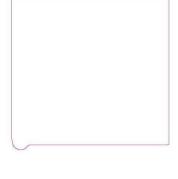
Stop use and ask a doctor if excessive irritation of the skin develops

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions • clean 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

Inactive ingredients butylene glycol, fragrance, hamamalis virginiana (witch hazel) extract, hydroxypropyl beta cyclodextrin, melaleuca alternifolia (tea Tree) leaf oil, menthol, SD alcohol 40-B, water





Drug Facts (continued)

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CLARITY CLEAR SKIN ESSENTIALS ACNE SPOT TREATMENT

salicylic acid cream

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:54473-225

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength

SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ) SALICYLIC ACID 0.156 g in 8.9 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
HAMAMELIS VIRGINIANA TOP (UNII: UDA30A2JJY)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
MENTHOL (UNII: L7T10EIP3A)	

l	Packaging					
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
		NDC:54473- 225-01	8.9 mL in 1 BOTTLE, WTH APPLICATOR; Type 0: Not a Combination Product	01/01/2018		

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph final	part333D	09/13/2012				

Labeler - Melaleuca Inc. (139760102)

Registrant - Melaleuca Inc. (079711683)

Establishment					
Name	Address	ID/FEI	Business Operations		
Melaleuca Inc.		079711683	manufacture(54473-225)		

Revised: 1/2023 Melaleuca Inc.