PROACTIV ACNE BODY BAR- salicylic acid soap ALCHEMEE, LLC

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.

Proactiv Acne Body Bar

Drug Facts

Active ingredient

Salicylic acid 2%

Purpose

Acne treatment

Use

for the management of acne

Warnings

For external use only

When using this product

- skin irritation and dryness are more likely to occur if you use another topical acne medication at the same time. If irritation occurs, only use one topical acne medication at a time.
- avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water.

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

Directions

- Sensitivity Test for a new user: Apply product sparingly to one or two small affected areas during the first 3 days. If no discomfort occurs, follow the directions stated below.
- cover the entire affected area with a thin layer <u>and rinse thoroughly</u> one to three times daily.
- because excessive drying of the skin may occur, start with one application daily, then gradually increase to two 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

sodium palmate, sodium palm kernelate, water, glycerin, sodium gluconate, palm acid, fragrance, sodium chloride, titanium dioxide, bambusa arundinacea stem extract, palm kernel acid, simmondsia chinensis (jojoba) seed oil, camellia sinensis leaf extract, opuntia ficus-indica seed oil

Questions or comments?

1-800-950-4695

Distributed by Alchemee LLC Santa Monica, CA 90401 Made in the USA of Foreign and Domestic Components Questions? 1-800-950-4695 proactiv.com • Proactiv is a registered trademark of Taro Pharmaceuticals U.S.A., Inc.

PRINCIPAL DISPLAY PANEL - 127 g Bar Carton

proactiv®

Acne Body Bar

Salicylic acid acne treatment

Clears up acne blemishes

Net wt. 4.50 OZ. 127 g



PROACTIV ACNE BODY BAR

salicylic acid soap

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11410-400	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	2 mg in 100 g		
Inactive Ingredients				
Ingredient Name		Strength		
Sodium Palmate (UNIII: S0A6004K37)				

 Sodium Palmate (UNII: S0A6004K3Z)
 Sodium Palm Kernelate (UNII: 6H91L1NXTW)

 Water (UNII: 059QF0K00R)
 Glycerin (UNII: PDC6A3C00X)

Palm Acid (UNII: B6G0Y5Z616)	
Titanium Dioxide (UNII: 15FIX9V2JP)	
Bambusa Bambos Stem (UNII: NRA4497HC5)	
Palm Kernel Acid (UNII: 79P21R4317)	
Jojoba Oil (UNII: 724GKU717M)	
Green Tea Leaf (UNII: W2ZU1RY8B0)	
Opuntia Ficus-Indica Seed Oil (UNII: 1XGW49AK2J)	
Sodium Chloride (UNII: 451W47IQ8X)	
Sodium Gluconate (UNII: R6Q3791S76)	

Packaging

#	ltem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11410- 400-00	1 in 1 CARTON	06/01/2022	06/30/2024
1		127 g in 1 APPLICATOR; Type 0: Not a Combination Product		
Marketing Information				
	Marketing	Application Number or Monograph	Marketing Start	Marketing End

Category	Citation	Date	Date
OTC MONOGRAPH FINAL	part333D	06/01/2022	06/30/2024

Labeler - ALCHEMEE, LLC (080216357)

Establishment					
Name	Address	ID/FEI	Business Operations		
Twincraft Inc		093248870	manufacture(11410-400)		

Revised: 8/2023

ALCHEMEE, LLC