

X OUT CLEANSING BODY BAR- salicylic acid soap
THE PROACTIV COMPANY 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.

X[®] Out Cleansing Body Bar

Drug Facts

Active ingredient

Salicylic Acid 1%

Purpose

Acne Treatment

Use

for the management of acne

Warnings

For external use only

When using this product

- do not use this product more than three times per day.
- 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.

Stop use and ask a doctor

If irritation becomes severe.

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 above.
- apply a small amount to dampened skin.
- cover the entire affected area with a thin layer and rinse thoroughly 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

sodium cocoyl isethionate, stearic acid, water, sodium isethionate, fragrance, cocamidopropyl hydroxysultaine, sodium chloride, galactoarabinan, disodium EDTA, pentasodium pentetate, titanium

dioxide

Questions or comments?

Within US **1-800-524-7952**

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PRINCIPAL DISPLAY PANEL - 141 g Applicator Carton

X®

OUT

**CLEANSING
BODY BAR**

From the Makers of Proactiv®

salicylic acid acne treatment

5.0 OZ. • 141 g

Drug Facts (continued)

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X OUT CLEANSING BODY BAR

salicylic acid soap

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11410-007
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 mg in 100 g

Inactive Ingredients

Ingredient Name	Strength
SODIUM COCOYL ISETHIONATE (UNII: 518XTE8493)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
WATER (UNII: 059QF0K00R)	
SODIUM ISETHIONATE (UNII: 3R36J71C17)	
COCAMIDOPROPYL HYDROXYSULTAINE (UNII: 62V75NI93W)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
PENTASODIUM PENTETATE (UNII: 961TOZ5L7T)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
Galactoarabinan (UNII: SL4SX1O487)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11410-007-37	1 in 1 CARTON	12/31/2012	
1		141 g in 1 APPLICATOR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part333D	12/31/2012	

Labeler - THE PROACTIV COMPANY LLC (080216357)

Establishment

Name	Address	ID/FEI	Business Operations
Bradford Soap Works		001201045	manufacture(11410-007)

Revised: 12/2017

THE PROACTIV COMPANY LLC