

X OUT CLEANSING BODY BAR- salicylic acid soap
Guthy-Renker 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

- 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

- 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.
- *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.

Inactive ingredients

sodium cocoyl isethionate, stearic acid, water, sodium isethionate, fragrance, cocamidopropyl hydroxysultaine, sodium chloride, galactoarabinan, polyethylene, disodium EDTA, pentasodium pentetate, titanium dioxide (CI 77891)

Questions or comments?

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

Dist. by: Guthy-Renker® LLC • PO Box 14383 Palm Desert, CA 92255-4383

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

Active ingredient: Salicylic acid 1%
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.

Stop use and ask a doctor if • irritation becomes severe.

Keep out of reach of children.
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Directions
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CLEANSING BODY BAR

From the Makers of Proactiv®

salicylic acid acne treatment
 5.0 OZ. • 141 g

Lift Here

Drug Facts (continued)

Inactive ingredients sodium cocoyl isethionate, stearic acid, water (aqua), sodium isethionate, fragrance (parfum), cocamidopropyl hydroxysulfate, sodium chloride, galactarabinan, polyethylene, disodium EDTA, pentasodium pentate, titanium dioxide (CI 77891)

Questions or comments?
 Within US 1-800-524-7952

Dist. by: Gundry-Perkare LLC • PO Box 14323 Palm Desert, CA 92255-4323
 XOut.com/reorder • Made in the USA of Foreign and Domestic Components
 XOut is a trademark in the United States and may be a trademark in other countries.

01.2020

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)	
CO CAMIDO PROPYL HYDRO XYSULTAINE (UNII: 62V75NI93W)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
PENTASODIUM PENTETATE (UNII: 961TOZ5L7T)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11410-007-37	1 in 1 CARTON		
1		141 g in 1 APPLICATOR		

Marketing Information

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

Labeler - Guthy-Renker LLC (608315453)

Revised: 1/2013

Guthy-Renker LLC