

PROACTIV 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.

Proactiv 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 a 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 below.
- 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 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 **1-800-950-4695**

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Company Sàrl

PRINCIPAL DISPLAY PANEL - 150 g Bar Carton

proactiv®

CLEANSING

BODY

BAR

Net wt. 5.25 OZ. 150 g

salicylic acid acne treatment

Drug Facts
Active ingredient Salicylic acid 1%.....Acne treatment
Purpose Use for the management of acne
Warnings For external use only
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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, get right away.

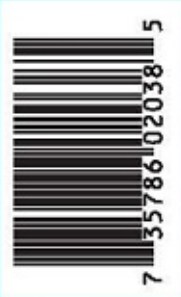
Drug Facts
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Inactive ingredients sodium cocoyl isethionate, stearic acid, water, sodium lauryl sulfate, sodium chloride, galactarabamine, disodium EDTA, pentasodium pentate, titanium dioxide
Questions or comments? Within US 1-800-950-6555

proactiv.

CLEANSING
 BODY BAR

Net wt. 5.25 OZ. 150 g

salicylic acid acne treatment



This soap-free cleansing bar contains acne-fighting salicylic acid to help clear pores as well as treat and help prevent new acne blemishes on the face and body.
 sulfate-free ■ dermatologist tested ■ non-comedogenic

KEY INGREDIENTS:

Salicylic Acid – an acne medicine that penetrates the follicle and encourages the shedding of dead skin cells, helping keep the pores clear of cellular debris. Clears up acne blemishes and helps prevent new ones from forming.

Cleansing Agent – mild, high-foaming cleansing ingredient derived from coconut oil, making Proactiv Cleansing Body Bar soap-free and surfactant-free.

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TIPS: Wet hands and work bar until it lathers. Apply to dampened skin, gently massaging in an upward circular motion. Rinse thoroughly with warm water and pat dry with a clean towel. Can be used twice daily. If bothersome dryness or peeling occurs, reduce application use to once a day. Can be used all over the face and body, or on targeted areas. If using during the day, follow with a sunscreen.

PRINCIPAL DISPLAY PANEL - 79 g Bar Carton

proactiv®
 CLEANSING

**BODY
BAR**

Net wt. 2.7 OZ. 79 g
salicylic acid acne treatment

Drug Facts (continued)

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 and dose thoroughly 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 cocoyl isethionate, stearic acid, water, sodium sodium chloride, galactarabinan, disodium EDTA, pentasodium pentetate, titanium dioxide

Questions or comments?
Within US 1-800-551-9955

Drug Facts

Active ingredient
Salicylic acid 1%..... Acne treatment

Purpose
Use for the management of acne

Warnings
For external use only

When using this product
■ do not use this product more than three times a 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.

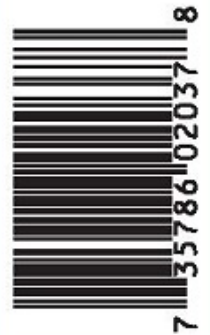
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

proactiv.

CLEANSING
BODY BAR

Net wt. 2.7 OZ. 79 g

salicylic acid acne treatment



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PA.01113

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PROACTIV CLEANSING BODY BAR

salicylic acid soap

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11410-025
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: 059QF0KO0R)	
SODIUM ISETHIONATE (UNII: 3R36J71C17)	
CO CAMIDO PROPYL HYDRO XYSULTAINE (UNII: 62V75NI93W)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
GALACTO ARABINAN (UNII: SL4SX1O487)	
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:11410-025-00	1 in 1 CARTON	06/01/2013	
1		150 g in 1 APPLICATOR; Type 0: Not a Combination Product		
2	NDC:11410-025-05	1 in 1 CARTON	06/01/2013	
2		79 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	06/01/2013	

Labeler - THE PROACTIV COMPANY LLC (080216357)**Establishment**

Name	Address	ID/FEI	Business Operations
Bradford Soap Works, Inc.		001201045	manufacture(11410-025)