SUPER BUMP RELIEF- benzoyl peroxide and salicylic acid cream Elements Personal Care, 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.

Super Bump Relief

Active ingredient

Benzoyl Peroxide 4% Salicylic Acid 3%

Purpose

Elimination of razor bumps and prevention of ingrown hairs

Uses

Elimination of razor bumps and prevention of ingrown hairs

Warnings

Avoid contact with eyes or fabric.

Keep out of reach of children.

Directions

After shaving with a razor or clippers, apply SBR on the entire shaved area, exfoliate with finger tips for 5 minutes, then rinse well or remove with a white wet cloth. In case of severe out-break of folliculitis, apply SBR, exfoliate and leave on overnight and remove with white wet cloth in the morning.

Inactive ingredients

Water (Aqua), Glycerin, Alcohol Denat, Propylene Glycol, Magnesium Sulfate Hepta-hydrate, Triethanolamine, Aloe Barbadensis Leaf Extract, Methylparaben, Hamamelis Virginiana (Witch Hazel) Extract, Cinnamomum Camphora (Camphor) Oil, Xanthan Gum, Carbomer, Titanium Dioxide, Magnesium Aluminum Silicate, Imidazolidinyl Urea.

Package/Label Principal Display Panel - Bottle Label



Developed for The Elimination of Razor Bumps

and

The Prevention of Ingrown Hairs

Doctor Recommended Net Wt. 4oz. (112.9 gr.) Directions: After shaving with a razor or clippers, apply SBR on the entire shaved area, exfoliate with finger tips for 5 minutes, then rinse well or remove with a white wet cloth. In case of severe out-break of folliculitis, apply SBR, exfoliate and leave on overnight and remove with white wet cloth in the morning.

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Manufactured: Elements Inc. N.D.C. 65840 Maxamillion's Gentlemen's Quarters Barber Parlor

Bottle Label

Super Bump Relief Developed for The Elimination of Razor Bumps and The Prevention of Ingrown Hairs Doctor Recommended Net Wt. 4 oz. (112.9 gr.) Manufactured: Elements Inc. N.D.C. 65840 Maxamillion's Gentlemen's Quarters Barber Parlor

SUPER BUMP RELIEF					
benzoyl peroxide and salicylic acid	l cream				
Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)		NDC:65840-	-100
Route of Administration	TOPICAL				
Active Ingredient/Active Moi	ety				
I	ngredient Name		Basis o	f Strength	Strength

BENZOYL PEROXIDE (UNII: W9WZN9A0GM) (BENZOYL PEROXIDE - UNII:W9WZN9A0GM)	BENZOYL PEROXIDE	$4 \ g \ in \ 100 \ g$
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	3 g in 100 g

Inactive Ingredients					
	Ingredient Nam	ie			Strength
WATER (UNII: 059QF0KO	0 R)				
ALCOHOL (UNII: 3K9958	V90M)				
PROPYLENE GLYCOL (U	NII: 6DC9Q167V3)				
MAGNESIUM SULFATE H	EPTAHYDRATE (UNII: SK47B8698T	7)			
TROLAMINE (UNII: 903K	93S3TK)				
ALOE VERA LEAF (UNII: 2	ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)				
METHYLPARABEN (UNII:	A2I8C7HI9T)				
CAMPHOR OIL (UNII: 7512	ZZ8 Y727)				
XANTHAN GUM (UNII: TT	V12P4NEE)				
TITANIUM DIO XIDE (UNI	I: 15FIX9 V2JP)				
MAGNESIUM ALUMINUM	SILICATE (UNII: 6M3P64V0NC)				
IMIDUREA (UNII: M62980)	7ATL)				
Packaging					
# Item Code	Package Description	Marketing	g Start Date	Mar	keting End Date
1 NDC:65840-100-01	113 g in 1 BOTTLE				
Marketing Inform	nation				
Marketing Category	Application Number or Monog	raph Citation	Marketing Star	t Date	Marketing End Date
OTC monograph not final	part333D		06/08/2011		

Labeler - Elements Personal Care, Inc. (018721058)

Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing, Inc.		793406000	MANUFACTURE

Revised: 6/2011

Elements Personal Care, Inc.