SPRINJENE WHITE BOOST-sodium fluoride paste, dentifrice Health and Natural Beauty USA Corp

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.

SprinJene™ White Boost

Drug Facts

Active Ingredient

Sodium Fluoride 0.243% (0.15% w/v fluoride ion)

Purpose

Anticavity

Use

Helps in the prevention of caries

Warnings

Keep out of reach of children under 6 years of age

If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Directions

Supervise children as necessary until capable of using without supervision

Adults and children 2 years of age and older brush teeth thoroughly, preferably after each meal or at least twice a day as directed by a dentist or physician.

Children under 2 to 6 years instruct in good brushing and rinsing habbits (to minimize swallowing).

Children under 2 years do not use unless directed by a dentist or physician.

Inactive Ingredients

Water, hydrated silica, glycerin, sorbitol, sodium lauryl sulfate, flavor, cellulose gum, zinc oxide, tetrasodium pyrophosphate, black seed oil, zinc citrate, titanium dioxide, xanthan gum, sodium saccharin

Questions or comments?

Call toll free 1-844-3-462872 www.sprinjene.com

Dist. by: Health and Natural Beauty USA Corp Piscataway, NJ 08854

PRINCIPAL DISPLAY PANEL - 142 g Tube Carton

NEW

 $SprinJene^{\mathrm{TM}}$

Fluoride Toothpaste

NET WT 5.0 OZ (142 g)

Bursting with the unique benefits of **Black Seed Oil**

CERTIFIED VEGAN VEGAN.ORG

White Boost Paste

NEW

prinjene"

Bursting with the unique benefits of Black Seed Oil

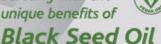
White Boost @ 100

NET WI 5.0 OZ (142 g)

NEW



Bursting with the unique benefits of



NET WT 5.0 OZ (142 g)

White Boost

You'll love the way your mouth feels! Find out more at sprinjene.com

✓ Fights cavities

- ✓ Whitens teeth
- Freshens breath
- Helps remove surface stains
- ✓ Helps give you a healthy mouth

Certified.









Kosher Gluten-Free

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Drug Facts (continued)

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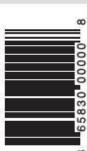
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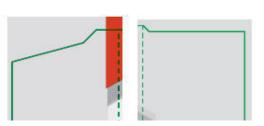
MADE IN U.S.A.

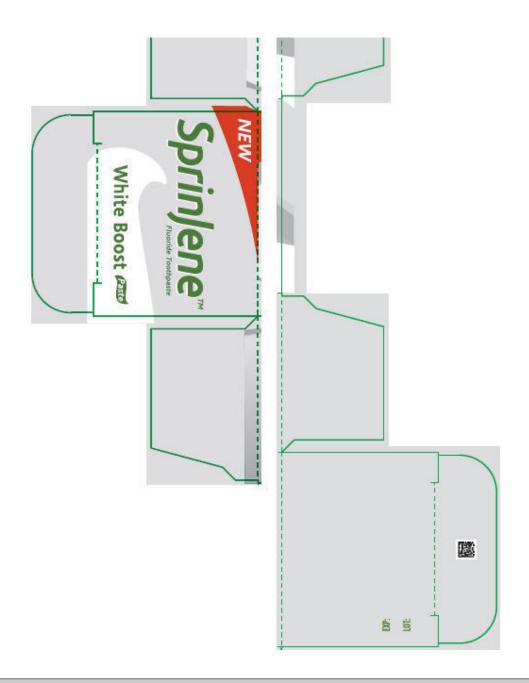












SPRINJENE WHITE BOOST

sodium fluoride paste, dentifrice

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63404-1116	
Route of Administration	DENTAL			

Active Ingredient/Active Moiety				
	Ingredient Name	Basis of Strength	Strength	
	Sodium Fluoride (UNII: 8ZYQ1474W7) (Fluoride Ion - UNII:Q80VPU408O)	Fluoride Ion	1.5 mg in 1 g	

Inactive Ingredients	
Ingredient Name	Strength

Water (UNII: 059QF0KO0R)				
Hydrated Silica (UNII: Y6O7T4G8P9)				
Glycerin (UNII: PDC6A3C0OX)				
Sorbitol (UNII: 506T60A25R)				
Sodium Lauryl Sulfate (UNII: 368GB5141J)				
Carboxymethylcellulose Sodium (UNII: K679OBS311)				
Zinc Oxide (UNII: SOI2LOH54Z)				
Guizotia Abyssinica Seed Oil (UNII: QX0GL46299)				
Sodium Pyrophosphate (UNII: O352864B8Z)				
Titanium Dioxide (UNII: 15FIX9 V2JP)				
Zinc Citrate (UNII: K72I3DEX9B)				
Xanthan Gum (UNII: TTV12P4NEE)				
Saccharin Sodium (UNII: SB8ZUX40TY)				

Product Characteristics					
Color	WHITE	Score			
Shape		Size			
Flavor	MINT (Mint/Clove)	Imprint Code			
Contains					

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:63404-1116-1	1 in 1 CARTON				
1		142 g in 1 TUBE; Type 0: Not a Combination Product				
2	NDC:63404-1116-2	1 in 1 CARTON				
2		42 g in 1 TUBE; Type 0: Not a Combination Product				

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH FINAL	part355	10/10/2014		

Labeler - Health and Natural Beauty USA Corp (079129688)

Establishment				
Name	Address	ID/FEI	Business Operations	
Health and Natural Beauty USA Corp		079129688	MANUFACTURE(63404-1116)	

Revised: 2/2015 Health and Natural Beauty USA Corp