SPRINJENE HEALTH BOOST- sodium monofluorophosphate 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® Health Boost

Drug Facts

Active Ingredient

Sodium Monofluorophosphate 0.76% (0.15% W/V fluoride ion)

Purpose

Anticavity

Use

Helps in the prevention of cavities

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 2-6 years old instruct in good brushing and rinsing habits (to minimize swallowing.)

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

Inactive Ingredients

Aqua, hydrated silica, sorbitol, glycerin, xylitol, erythritol, poloxamer 407, cocamidopropyl betaine, flavor, cellulose gum, zinc citrate, zinc oxide, sodium lauryl sulfoacetate, nigella sativa oil (black seed oil), titanium dioxide, xanthan gum

Questions or comments?

Call toll free 1-844-346-2872 www.sprinjene.com

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

PRINCIPAL DISPLAY PANEL - 142 g Tube Carton

SprinJene®

Fluoride Toothpaste

NET WT 5 OZ (142g)

Bursting with the unique benefits of

Black Seed Oil

CERTIFIED VEGAN VEGAN.ORG

Health Boost *Paste*



Bursting with the unique benefits of Black Seed Oil



Bursting with the unique benefits of



Black Seed Oil

Sprin/ene®

NET WT 5 OZ (142 g)

Health Boost

SprinJene^{*}

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

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

Certified:









No SLS. No TSPP, No Saccharine

Drug Facts

Active Ingredient Sodium Monofluorophosphate 0.76% (0.15% W/V fluoride ion). Purpose

Helps in the prevention of cavities

Warnings
Keep out of reach of children under 5 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 w ithout 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 2-6 years old instruct in good brushing and rinsing habits (to minimize swallowing.)

Drug Facts (continued)

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

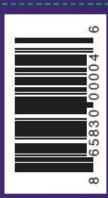
Inactive Ingredients

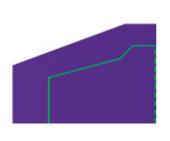
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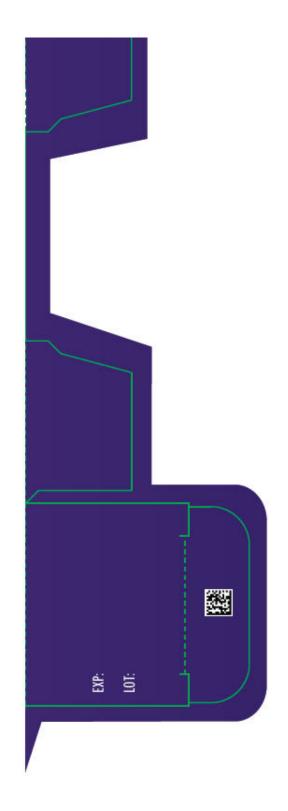
MADE IN U.S.A.











SPRINJENE HEALTH BOOST

sodium monofluorophosphate paste, dentifrice

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63404-1108
Route of Administration	DENTAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Sodium Monofluorophosphate (UNII: C810JCZ56Q) (Fluoride Ion - UNII:Q80VPU408O)	Fluoride Ion	1.5 mg in 1 g	

Inactive Ingredients		
Ingredient Name	Strength	
Water (UNII: 059QF0KO0R)		
Hydrated Silica (UNII: Y6O7T4G8P9)		
Sorbitol (UNII: 506T60A25R)		
Glycerin (UNII: PDC6A3C0OX)		
Xylitol (UNII: VCQ006KQ1E)		
Erythritol (UNII: RA96B954X6)		
Poloxamer 407 (UNII: TUF2IVW3M2)		
Cocamidopropyl Betaine (UNII: 50CF3011KX)		
Carboxymethylcellulose Sodium, Unspecified (UNII: K6790BS311)		
Zinc Citrate (UNII: K72I3DEX9B)		
Zinc Oxide (UNII: SOI2LOH54Z)		
Sodium Lauryl Sulfoacetate (UNII: D0Y70F2B9J)		
Nigella Sativa Seed Oil (UNII: CS4U38E731)		
Titanium Dioxide (UNII: 15FIX9V2JP)		
Xanthan Gum (UNII: TTV12P4NEE)		

Product Characteristics			
Color	WHITE	Score	
Shape		Size	
Flavor	MINT (Minty)	Imprint Code	
Contains			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:63404- 1108-1	1 in 1 CARTON	07/01/2016		
1		142 g in 1 TUBE; Type 0: Not a Combination Product			
2	NDC:63404- 1108-2	1 in 1 CARTON	07/01/2016		
2		42 g in 1 TUBE; Type 0: Not a Combination Product			

Marketing Information			
Marketing Application Number or Monograph Category Citation		Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part355	07/01/2016	

Labeler - Health and Natural Beauty USA Corp (079129688)

Establishment				
Name	Address	ID/FEI	Business Operations	
Health and Natural Beauty USA Corp		079129688	MANUFACTURE(63404-1108)	

Revised: 2/2023 Health and Natural Beauty USA Corp