

SPRINJENE NATURAL SENSITIVITY RELIEF- sodium monofluorophosphate and potassium nitrate 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® Natural
Sensitivity Relief**

Drug Facts

<i>Active Ingredient</i>	<i>Purpose</i>
Sodium Monofluorophosphate: 0.76% (0.14% w/v fluoride ion)	Anticavity
Potassium Nitrate: 5%	Antihypersensitivity

Use

Helps remove surface stains with regular brushing, and helps prevent plaque buildup.

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 to 6 years 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

Xylitol, Aqua, Glycerin, Precipitated Natural Calcium Carbonate, Hydrated Silica, Zemea (1,3-Propanediol made from Corn), Potassium Cocoate (made from Coconut Oil), Flavor, Zinc Citrate, Xanthan Gum, Acacia Gum, Zinc Oxide, Black Seed Oil (Nigella sativa), Citric Acid, Stevia

Questions or comments?

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

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

PRINCIPAL DISPLAY PANEL - 99 g Tube Carton

***SprinJene® +Sensitivity
Natural
Relief***

CAVITY PROTECTION

TOOTHPASTE

with **Black Seed Oil** (*Nigella sativa*) & **Zinc**

Helps Relieve Teeth Sensitivity | Remineralizes Enamel

Helps Dry Mouth | Cleans Teeth | Freshens Breath

NET WT 3.5 OZ (99 g)

Made in USA

**To accommodate
the needs of
various lifestyles.**

CERTIFIED VEGAN

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Vegan

GLUTEN-FREE

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CERTIFIED

Gluten

Free

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Kosher

HALAL

Halal

Certified

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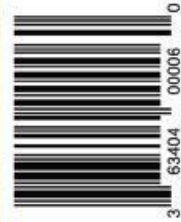
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Drug Facts (continued)

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MADE IN USA



SprinJene[®]+Sensitivity Natural Relief

— CAVITY PROTECTION —

TOOTHPASTE

with **BLACK SEED OIL** (*Nigella sativa*) & **ZINC**
HELPS RELIEVE TEETH SENSITIVITY | REMINERALIZES ENAMEL
HELPS DRY MOUTH | CLEANS TEETH | FRESHENS BREATH

NET WT 3.5 OZ (99 g)

Made in USA

To accommodate the needs of various lifestyles.



Vegan

Gluten Free



Kosher

Halal

— Certified —

— with —

- BIRCH TREE XYLITOL
- ACACIA GUM
- BLACK SEED OIL
- ZINC

SprinJene was developed by a PhD scientist with a long-standing career in oral care products. The SprinJene mission is to create premium oral care products that are uniquely formulated using SCIENCE + NATURE. Our patented formula includes black seed oil, which has over 3,000 years of legendary health benefits.

MAKING THE WORLD SMILE™

SprinJene[®]+Sensitivity
Natural Relief

— CAVITY PROTECTION —

TOOTHPASTE

Bursting with the unique benefits of

BLACK SEED OIL
(*Nigella sativa*)

- HELPS RELIEVE TEETH SENSITIVITY
- REMINERALIZES ENAMEL
- FRESHENS BREATH
- HELPS DRY MOUTH
- SLS FREE
- PRESERVATIVE FREE
- DYE FREE
- USES NATURAL FLAVOR

Also contains **ZINC**



Halal



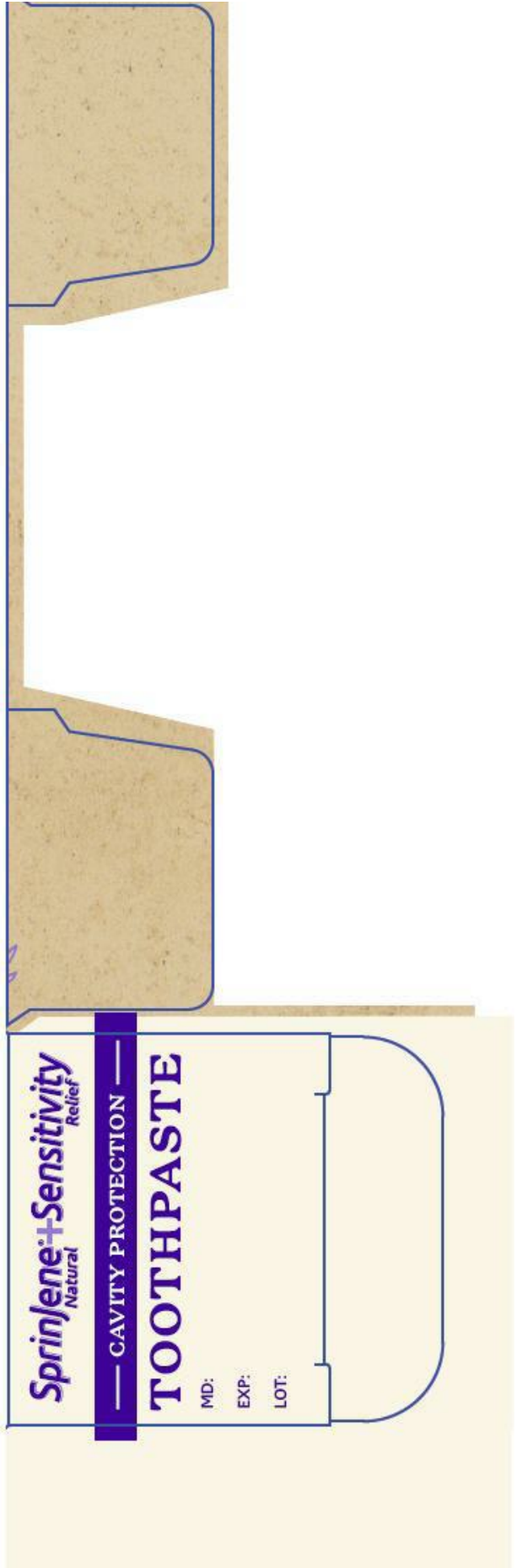
Kosher



Gluten Free



Vegan



SPRINJENE NATURAL SENSITIVITY RELIEF

sodium monofluorophosphate and potassium nitrate paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63404-1942
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
Potassium Nitrate (UNII: RU45X2JN0Z) (NITRATE ION - UNII:T93E9Y2844)	Potassium Nitrate	50 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0K00R)	
Glycerin (UNII: PDC6A3C0OX)	
Calcium Carbonate (UNII: H0G9379FGK)	
Silicon Dioxide (UNII: ETJ7Z6XBU4)	
Propanediol (UNII: 5965N8W85T)	
Potassium Cocoate (UNII: F8U72V8ZXP)	
Zinc Citrate (UNII: K72I3DEX9B)	
Xanthan Gum (UNII: TTV12P4NEE)	
Acacia (UNII: 5C5403N26O)	
Zinc Oxide (UNII: SOI2LOH54Z)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
STEVIA REBAUDIUNA LEAF (UNII: 6TC6NN0876)	

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63404-1942-1	1 in 1 CARTON	07/01/2017	
1		99 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 not final	part356	07/01/2017	

Labeler - Health and Natural Beauty USA Corp (079129688)

Establishment

Name	Address	ID/FEI	Business Operations
Health and Natural Beauty USA Corp		079129688	MANUFACTURE(63404-1942)

Revised: 9/2017

Health and Natural Beauty USA Corp