

**SPRINJENE NATURAL- 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®**  
**Natural**

***Drug Facts***

**Active Ingredient**

Sodium Monofluorophosphate: 0.76% (0.14% 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 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**

Aqua, Xylitol, Glycerin, Silica, Calcium Carbonate, Acacia Gum, Corn Zemea (1,3-Propanediol), Vegetable Betaine (Cocamidopropyl Betaine), Flavor, Sodium Bicarbonate, Zinc Citrate, Guar Gum, Xanthan Gum, Black Seed Oil (Nigella sativa), Zinc Oxide, Stevia Rebaudiana Extract, Pectin.

**Questions or comments?**

Call 1-844-346-2872 [www.sprinjene.com](http://www.sprinjene.com)

*Manufactured and Dist. by:*

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

**PRINCIPAL DISPLAY PANEL - 99 g Tube Carton**

**SprinJene®**

***Natural***

*with Fluoride*

**TOOTHPASTE**

with **BLACK SEED OIL** (*Nigella sativa*) & **ZINC**

CAVITY PROTECTION | REMINERALIZES ENAMEL | HELPS DRY MOUTH

NET WT 3.5 OZ (99 g)

Made in USA

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

**Certified:**

**CERTIFIED VEGAN**

**VEGAN.ORG**

**Vegan**

**GLUTEN-FREE**

**CERTIFIED**

**Gluten**

**Free**

**U**

**Kosher**

**HALAL**

**Halal**



### Drug Facts

**Active Ingredient** Purpose  
Sodium Monofluorophosphate: 0.76% (0.14% w/v fluoride ion).....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.

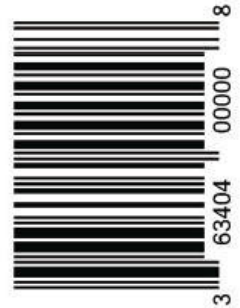
### Drug Facts (continued)

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** Aqua, Xylitol, Glycerin, Silica, Calcium Carbonate, Acacia Gum, Corn Zemea (1,3-Propanediol), Vegetable Betaine (Cocamidopropyl Betaine), Flavor, Sodium Bicarbonate, Zinc Citrate, Guar Gum, Xanthan Gum, Black Seed Oil (Nigella sativa), Zinc Oxide, Stevia Rebaudiana Extract, Pectin.

Questions or comments? Call 1-844-346-2872 [www.sprinjene.com](http://www.sprinjene.com)  
Manufactured and Dist. by:  
Health and Natural Beauty USA Corp.  
Piscataway, NJ 08854

MADE IN USA



# SprinJene<sup>®</sup> Natural

— with Fluoride —

## TOOTHPASTE

with BLACK SEED OIL (*Nigella sativa*) & ZINC

CAVITY PROTECTION | REMINERALIZES ENAMEL | HELPS DRY MOUTH

NET WT 3.5 OZ (99 g)

Made in USA

To accommodate the needs of various lifestyles.

Certified:



Vegan



Gluten Free



Kosher



Halal

- 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<sup>®</sup> Natural

— with Fluoride —

## TOOTHPASTE

Bursting with the unique benefits of

### BLACK SEED OIL (*Nigella sativa*)

- CAVITY PROTECTION
- REMINERALIZES ENAMEL
- FRESHENS BREATH
- HELPS DRY MOUTH
- SLS FREE
- PRESERVATIVE FREE
- DYE FREE

USES NATURAL FLAVOR

Also contains ZINC



Halal



Kosher



Gluten Free



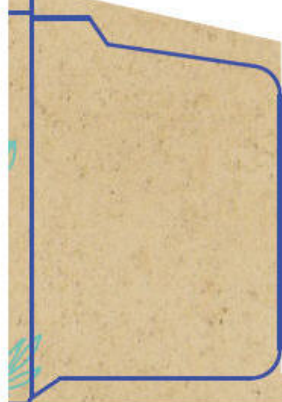
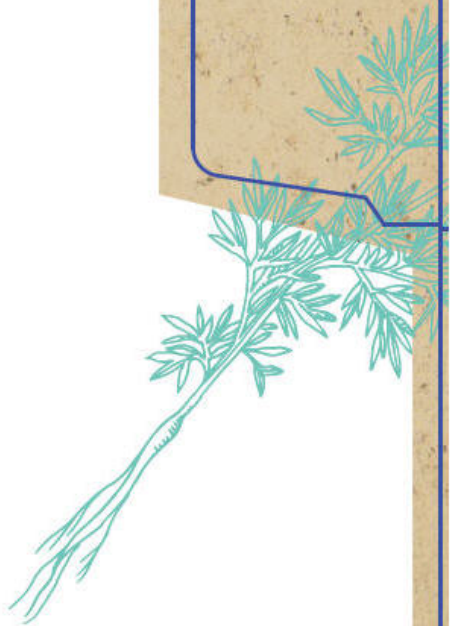
Vegan





**SprinJene®**  
Natural  
— with Fluoride —

**TOOTH PASTE**  
with  
**BLACK SEED OIL**  
(*Nigella sativa*)



**SprinJene®**  
Natural  
— with Fluoride —

MD:  
EXP:  
LOT:

# SPRINJENE NATURAL

sodium monofluorophosphate paste, dentifrice

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:63404-0201
<b>Route of Administration</b>	DENTAL		

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

Ingredient Name	Strength
<b>Water</b> (UNII: 059QF0KO0R)	
<b>Xylitol</b> (UNII: VCQ006KQ1E)	
<b>Glycerin</b> (UNII: PDC6A3C0OX)	
<b>Silicon Dioxide</b> (UNII: ETJ7Z6XBU4)	
<b>Calcium Carbonate</b> (UNII: H0G9379FGK)	
<b>Acacia</b> (UNII: 5C5403N26O)	
<b>Propanediol</b> (UNII: 5965N8W85T)	
<b>Cocamidopropyl Betaine</b> (UNII: 5OCF3011KX)	
<b>Sodium Bicarbonate</b> (UNII: 8MDF5V39QO)	
<b>Zinc Citrate</b> (UNII: K72I3DEX9B)	
<b>Guar Gum</b> (UNII: E89I1637KE)	
<b>Xanthan Gum</b> (UNII: TTV12P4NEE)	
<b>Zinc Oxide</b> (UNII: SOI2LOH54Z)	
<b>Pectin</b> (UNII: 89NA02M4RX)	

## Product Characteristics

<b>Color</b>	WHITE	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	MINT (Minty)	<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63404-0201-1	1 in 1 CARTON	02/01/2017	
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 FINAL	part355	02/01/2017	

**Labeler** - Health and Natural Beauty USA Corp (079129688)

## Establishment

Name	Address	ID/FEI	Business Operations
Health and Natural Beauty USA Corp		079129688	MANUFACTURE(63404-0201)

Revised: 1/2017

Health and Natural Beauty USA Corp