

SPRINJENE FRESH BOOST- sodium fluoride gel, 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™
Fresh 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 habits (to minimize swallowing).

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

Inactive Ingredients

Water, hydrated silica, sorbitol, glycerin, sodium lauryl sulfate, flavor, cellulose gum, tetrasodium pyrophosphate, zinc citrate, black seed oil, xanthan, sodium saccharin, mica, FD&C Blue No. 1, FD&C Yellow No. 5

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 - 130 g Tube Carton

NEW

Sprinjene™

Fluoride Toothpaste

*Bursting with the
unique benefits of*

Black Seed Oil

CERTIFIED VEGAN

VEGAN.ORG

Fresh Boost Gel

NET WT 4.6 OZ (130 g)

NEW

SprinJene™

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Bursting with the
unique benefits of
Black Seed Oil



Fresh Boost Gel

NEW

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NET WT 4.6 OZ (130 g)

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unique benefits of
Black Seed Oil



Fresh Boost Gel

SprinJene™

Fluoride Toothpaste

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:



Vegan



Halal



Kosher



Gluten-Free

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Drug Facts (continued)

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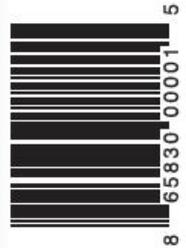
Inactive Ingredients

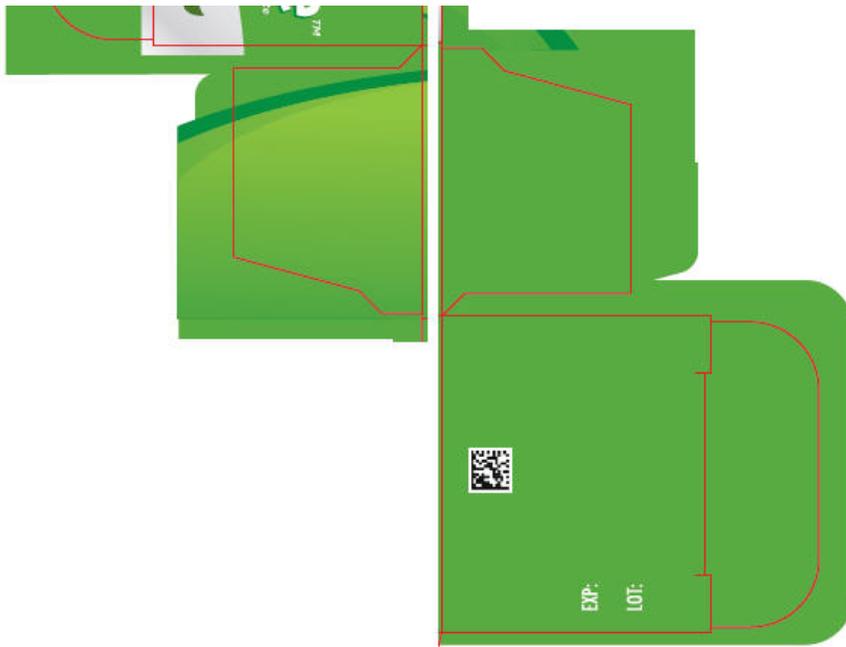
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Dist. by:
Health and Natural Beauty USA Corp
Piscataway, NJ 08854

MADE IN U.S.A.





SPRINJENE FRESH BOOST

sodium fluoride gel, dentifrice

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:63404-0910 |
| Route of Administration | DENTAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|---------------|
| Sodium Fluoride (UNII: 8ZYQ1474W7) (Fluoride Ion - UNII:Q80VPU4080) | 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, UNSPECIFIED (UNII: K679OBS311) | |
| Zinc Citrate (UNII: K72I3DEX9B) | |
| Guizotia Abyssinica Seed Oil (UNII: QX0GL46299) | |
| Sodium Pyrophosphate (UNII: O352864B8Z) | |
| Xanthan Gum (UNII: TTV12P4NEE) | |
| Saccharin Sodium (UNII: SB8ZUX40TY) | |
| Mica (UNII: V8A1AW0880) | |
| FD&C Blue No. 1 (UNII: H3R47K3TBD) | |
| FD&C Yellow No. 5 (UNII: I753WB2F1M) | |

Product Characteristics

| | | | |
|-----------------|--------------|---------------------|--|
| Color | GREEN | Score | |
| Shape | | Size | |
| Flavor | MINT (Minty) | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:63404-0910-1 | 1 in 1 CARTON | 10/10/2014 | |
| 1 | | 130 g in 1 TUBE; Type 0: Not a Combination Product | | |
| 2 | NDC:63404-0910-2 | 1 in 1 CARTON | 10/10/2014 | |
| 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(63404-0910) |

Revised: 2/2023

Health and Natural Beauty USA Corp