

SPRINJENE NATURAL TOTAL CARE CAVITY PROTECTION- sodium fluoride paste, dentifrice
Health and Natural Beauty USA Corp

SprinJene
Natural® Total Care Cavity Protection

DRUG FACTS

ACTIVE INGREDIENT

SODIUM FLUORIDE 0.243% (0.14 W/V FLUORIDE ION)

PURPOSE

ANTICAVITY

USE

HELPS IN THE PREVENTION OF CAVITIES. 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. INSTRUCT CHILDREN 2 TO 6 YEARS 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 (AQUA), HYDRATED SILICA, XYLITOL, GLYCERIN, 1,3 - PROPANEDIOL (ZEMEA - MADE FROM NON-GMO CORN), NATURAL PEPPERMINT OIL, ZINC CITRATE, XANTHAN GUM, SODIUM LAURYL SULFOACETATE (LAL), NIGELLA SATIVA (BLACK SEED OIL), ZINC OXIDE, STEVIA REBAUDIANA EXTRACT, TIO₂, ACACIA GUM, PUNICA GRANATUM SEED OIL (POMEGRANATE), THYMUS VULGARIS OIL (THYME), MELALEUCA ALTERNIFOLIA (TEA TREE) LEAF OIL

MANUFACTURED AND DIST BY : HEALTH AND NATURAL
BEAUTY USA CORP PISCATAWAY, NJ 08854

PRINCIPAL DISPLAY PANEL - 142 GM Tube Carton

SprinJene
Natural®

TOTAL CARE
CAVITY PROTECTION
TOOTHPASTE

BURSTING WITH THE UNIQUE BENEFITS OF
BLACK SEED OIL AND ZINC

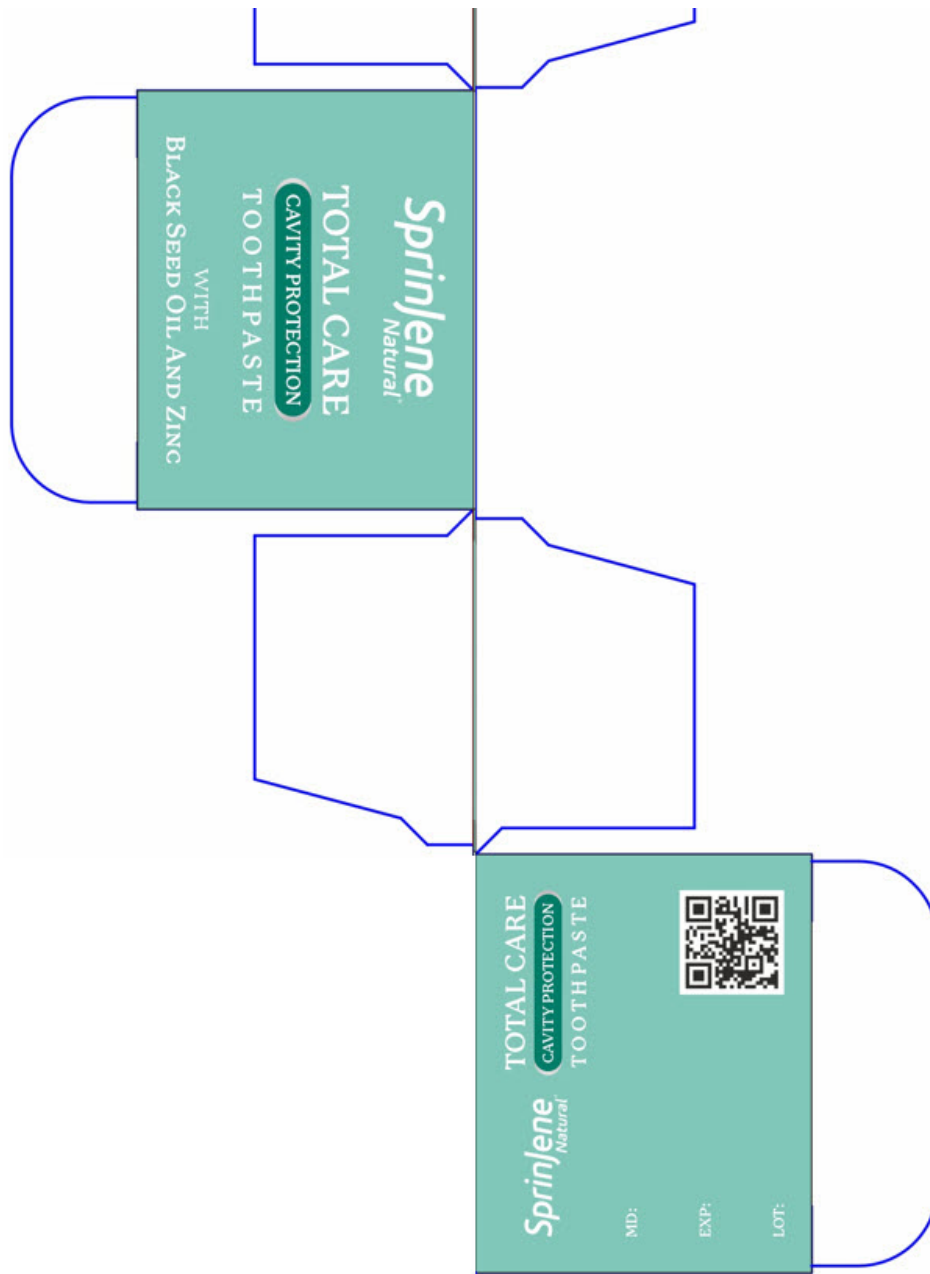
NET WT 5OZ (142GM)

- WHITENING
- REMINERALIZES ENAMEL
- FRESHENS BREATH
- HELPS DRY MOUTH
- SLS FREE
- PRESERVATIVE FREE
- DYE FREE
- NATURAL PEPPERMINT OIL

USDA
CERTIFIED
BIOBASED
PRODUCT
PRODUCT 100%

CERTIFIED VEGAN
VEGAN.ORG

GLUTEN-FREE
CERTIFIED



SPRINJENE NATURAL TOTAL CARE CAVITY PROTECTION

sodium fluoride paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63404-6319
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: 059QF0K00R)	
Hydrated Silica (UNII: Y6O7T4G8P9)	
Glycerin (UNII: PDC6A3C00X)	
Xylitol (UNII: VCQ006KQ1E)	
PROPANEDIOL (UNII: 5965N8W85T)	
Xanthan Gum (UNII: TTV12P4NEE)	
Zinc Citrate (UNII: K72I3DEX9B)	
Cocamidopropyl Hydroxysultaine (UNII: 62V75NI93W)	
Sodium Hydroxide (UNII: 55X04QC32I)	
Titanium Dioxide (UNII: 15FIX9V2JP)	
ACACIA (UNII: 5C5403N26O)	
ECHINACEA PURPUREA WHOLE (UNII: QI7G114Y98)	
SALVIA ROSMARINUS FLOWERING TOP (UNII: 8JM482TI79)	
THYME OIL (UNII: 2UK410MY6B)	
GOLDENSEAL (UNII: ZW3Z11D0JV)	

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor	PEPPERMINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63404-6319-1	1 in 1 CARTON	03/01/2024	
1		142 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 drug	M021	03/01/2024	

Labeler - Health and Natural Beauty USA Corp (079129688)

Establishment

Name	Address	ID/FEI	Business Operations
Health and Natural Beauty USA Corp		079129688	MANUFACTURE(63404-6319)