

**SPRINJENE NATURAL SENSITIVITY AND GUM- 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 & Gum**

DRUG FACTS

ACTIVE INGREDIENT

POTASSIUM NITRATE 5%

PURPOSE

ANTIHYPERSENSITIVITY

USE

HELPS REDUCE TOOTH AND GUM SENSITIVITY, 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®

SENSITIVITY & GUM

FLUORIDE FREE

TOOTHPASTE

BURSTING WITH THE UNIQUE BENEFITS OF
BLACK SEED OIL AND ZINC

- WHITENING
- 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

NET WT 5OZ (142GM)

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DRUG FACTS (CONTINUED)

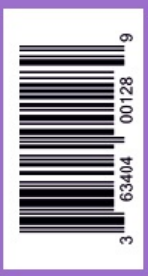
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CALL TOLL FREE
 1-844-346-2872
 VISIT: WWW.SPRINJENE.COM

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



SprinJene
Natural

SENSITIVITY & GUM

FLUORIDE FREE
TOOTHPASTE

BURSTING WITH THE UNIQUE BENEFITS OF
BLACK SEED OIL AND ZINC

NET Wt 5oz (142GM)

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



SprinJene
Natural

SPRINJENE IS THE INSPIRATION OF A PHD SCIENTIST WITH A LONG -STANDING CAREER DEVELOPING ORAL CARE PRODUCTS. OUR MISSION IS TO CREATE INNOVATIVE PREMIUM ORAL CARE PRODUCTS BY COMBINING THE POWER OF SCIENCE + NATURE. SPRINJENE'S UNIQUE PATENTED FORMULATION INCLUDES BLACK SEED OIL - KNOWN FOR IT'S LEGENDARY HEALTH BENEFITS FOR OVER 3000 YEARS - AND ZINC. EXPERIENCE A NATURAL, GENTLE, AND EFFECTIVE TOOTHPASTE THAT CLEANS YOUR TEETH AND LEAVES YOUR MOUTH FRESH.

MAKING THE WORLD SMILE NATURALLY®

- ☑ BIRCH TREE XYLITOL
- ☑ ACACIA GUM
- ☑ BLACK SEED OIL
- ☑ ZINC
- ☑ POMEGRANATE
- ☑ TEA TREE OIL
- ☑ THYME
- ☑ NATURAL PEPPERMINT OIL

SprinJene
Natural

SENSITIVITY & GUM
FLUORIDE FREE
TOOTHPASTE



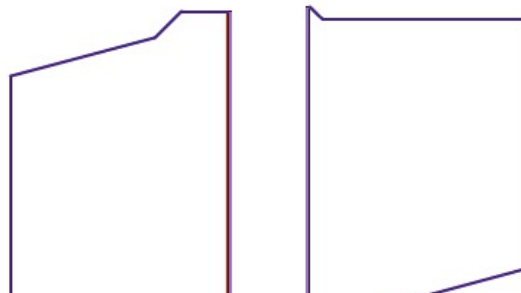
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 UNIQUE BENEFITS OF
**BLACK SEED OIL
 AND ZINC**

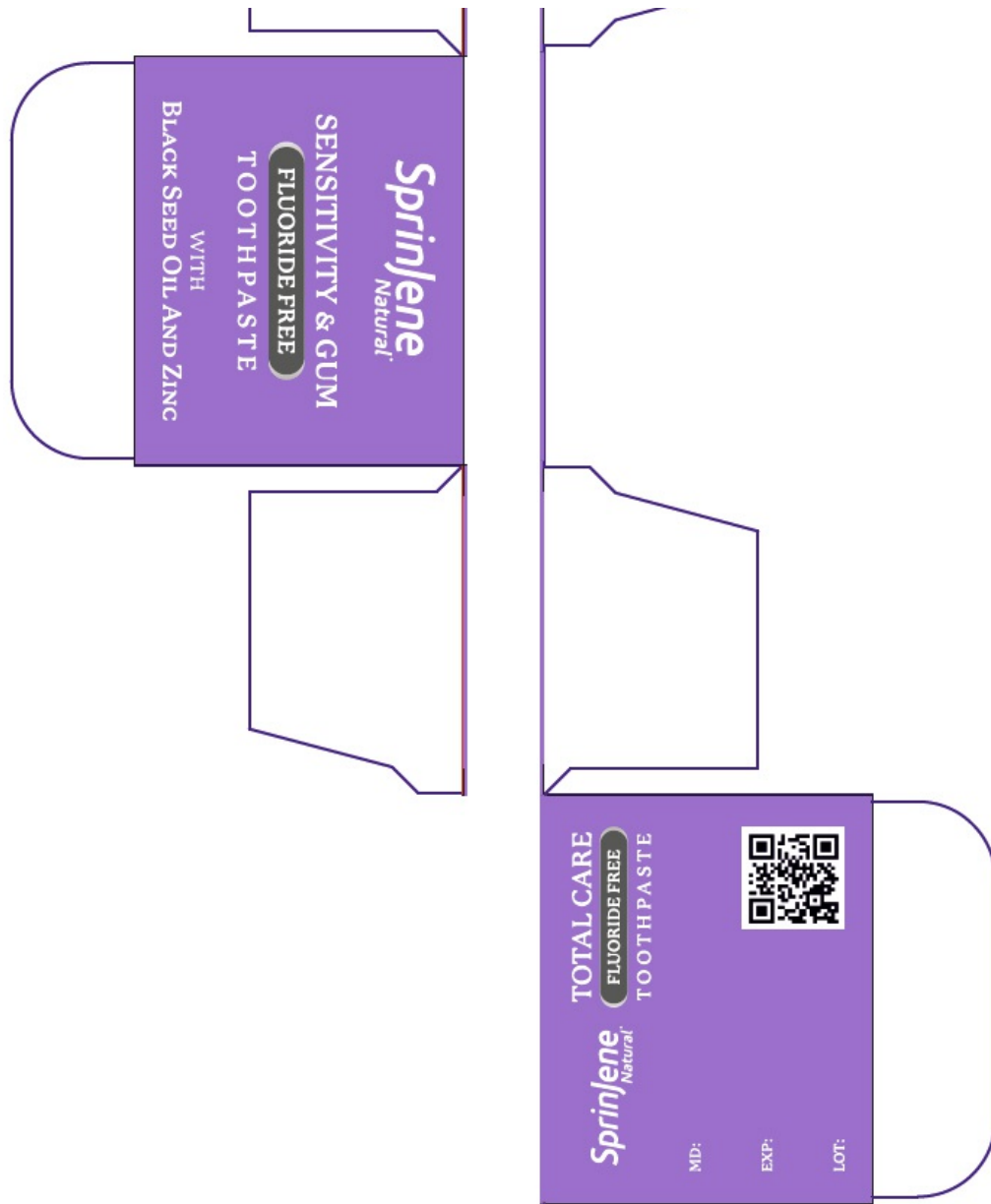
- ☑ POMEGRANATE
- ☑ TEA TREE OIL
- ☑ THYME

FREE FROM:

SLS • DYE • PRESERVATIVES

NATURAL PEPPERMINT OIL
 NET Wt 5oz (142GM)





SPRINJENE NATURAL SENSITIVITY AND GUM

potassium nitrate paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63404-1984
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Potassium Nitrate (UNII: RU45X2JN0Z) (NITRATE ION - UNII:T93E9Y2844)	Potassium Nitrate	50 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
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Water (UNII: 059QF0KO0R)
Hydrated Silica (UNII: Y6O7T4G8P9)
XYLITOL (UNII: VCQ006KQ1E)
Glycerin (UNII: PDC6A3C0OX)
PROPANEDIOL (UNII: 5965N8W85T)
Zinc Citrate (UNII: K72I3DEX9B)
Xanthan Gum (UNII: TTV12P4NEE)
SODIUM LAURYL SULFOACETATE (UNII: D0Y70F2B9J)
NIGELLA SATIVA SEED OIL (UNII: CS4U38E731)
Zinc Oxide (UNII: SOI2LOH54Z)
STEVIA SERRATA FLOWER OIL (UNII: 93Z447IP63)
Titanium Dioxide (UNII: 15FIX9V2JP)
Acacia (UNII: 5C5403N26O)
POMEGRANATE (UNII: 56687D1Z4D)
THYME OIL (UNII: 2UK410MY6B)
TEA TREE OIL (UNII: VIF565UC2G)

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

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63404-1984-1	1 in 1 CARTON	02/20/2021	
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 NOT FINAL	part356	02/20/2021	

Labeler - Health and Natural Beauty USA Corp (079129688)

Establishment			
Name	Address	ID/FEI	Business Operations
Health and Natural Beauty USA Corp		079129688	MANUFACTURE(63404-1984)