

MADE BY DENTISTS, INC. REBUILDING- potassium nitrate, sodium fluoride paste

Made By Dentists, Inc.

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.

Made By Dentists Rebuilding Toothpaste

Drug Facts

Active ingredient:

Potassium Nitrate 5.0%

Sodium Fluoride 0.24%

Purpose

Potassium Nitrate Desensitizer

Sodium Fluoride Anticavity

Use: Aids in the prevention of cavities. Helps Reduce painful sensitivity of teeth to cold, heat, acids, sweets, or contact.

Warnings:

Sensitive teeth may indicate a serious problem that may need prompt care by a dentist. See your dentist if the problem persists or worsens. Do not use this product longer than 4 weeks unless recommended by a dentist or doctor.

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:

- Adults and children 12 years of age and older:
Apply at least a 1-inch strip of the product onto a soft bristle toothbrush. Brush teeth thoroughly for at least 1 minute twice a day, (morning and evening) or as recommended by a dentist or doctor.
- Make sure to brush all sensitive areas of the teeth.
- Children under 12 years of age: Consult a dentist or doctor.

Inactive Ingredients:

Cellulose Gum, Citric Acid, Cocamidopropyl Betaine, Flavor, Hydrated Silica, Hydroxyapatite, Potassium Sorbate, Sodium Bicarbonate, Sodium Saccharin, Sodium Tripolyphosphate, Sorbitol,

Titanium Dioxide, Water, Xylitol

Questions? +1 (646) 980-6461

Rebuilding Toothpaste Product Labeling

Rebuilding Toothpaste

Made By Dentists[™]

Fresh Mint Flavor

NET WT 4.2 Oz / 120g

MADE IN THE USA

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439 S. Cedros Avenue, Suite 402.

Solana Beach, CA, 92075

Carton



Tube

do not place any objects in this area

W

Made By Dentists™



Professional Oral Care



Vegan
Friendly



100%
Recyclable



Cruelty
Free

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Sodium Fluoride 0.24% Anticavity

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Questions or comments?

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Rebuilding Toothpaste
Fluoride Anticavity

Fresh Mint
Flavor

NET WT 4.2 Oz / 120 g

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Solana Beach, California, 92075.

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MADE BY DENTISTS, INC. REBUILDING

potassium nitrate, sodium fluoride paste

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:75065-019

| | | | | |
|--|--|--|----------------------|--------------------|
| Route of Administration | | DENTAL | | |
| | | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| POTASSIUM NITRATE (UNII: RU45X2JN0Z) (NITRATE ION - UNII:T93E9Y2844) | | POTASSIUM NITRATE | 5 g in 100 g | |
| SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O) | | SODIUM FLUORIDE | 0.24 g in 100 g | |
| | | | | |
| Inactive Ingredients | | | | |
| Ingredient Name | | | Strength | |
| CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311) | | | | |
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) | | | | |
| COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX) | | | | |
| HYDRATED SILICA (UNII: Y6O7T4G8P9) | | | | |
| TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28) | | | | |
| POTASSIUM SORBATE (UNII: 1VPU26JZZ4) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| SACCHARIN SODIUM (UNII: SB8ZUX40TY) | | | | |
| SODIUM TRIPOLYPHOSPHATE ANHYDROUS (UNII: 9SW4PFD2FZ) | | | | |
| SORBITOL (UNII: 506T60A25R) | | | | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | | | | |
| WATER (UNII: 059QF0KO0R) | | | | |
| XYLITOL (UNII: VCQ006KQ1E) | | | | |
| | | | | |
| Product Characteristics | | | | |
| Color | | Score | | |
| Shape | | Size | | |
| Flavor | MINT | Imprint Code | | |
| Contains | | | | |
| | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:75065-019-06 | 1 in 1 CARTON | 01/24/2023 | |
| 1 | | 120 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 | | 01/24/2023 | |

Labeler - Made By Dentists, Inc. (117405870)

Registrant - Made By Dentists, Inc. (117405870)

Revised: 1/2023

Made By Dentists, Inc.