

**IODENT SENSITIVE EXTRA WHITENING- sodium fluoride potassium nitrate paste
United Exchange 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.

Active Ingredients

Purpose

Potassium nitrate 5%.....Antihypersensitivity

Sodium fluoride (0.15% w/v fluoride ion).....Anticavity

Uses

- builds increasing protection against painful sensitivity of the teeth due to cold, heat, acids, sweets or contact
- aids in the prevention of dental cavities

Warnings

Stop use and ask a dentist if

- the problem persists or worsens. Sensitive teeth may indicate a serious problem that may prompt care by a dentist
- pain/sensitivity still persists after 4 weeks of use

Keep out of reach of children. 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 product onto a soft bristle toothbrush
- brush teeth thoroughly for at least 1 minute twice a day (morning and evening), and not more than 3 times a day, or as recommended by a dentist or doctor. Make sure to brush all sensitive areas of the teeth. Minimize swallowing. Spit out after brushing.
- **children under 12 years of age:** consult a dentist or doctor

Other information

- store at room temperature 20-25°C (68-77°F)

Inactive ingredients

sorbitol, hydrated silica, water, PEG-1500, sodium lauryl sulfate, flavor, glycerin, cellulose gum, tetrasodium pyrophosphate, titanium dioxide, sodium benzoate, sodium hydroxide, sodium saccharin, trisodium phosphate, methylparaben, propylparaben

Distributed by:

United Exchange Corp.
17211 Valley View Ave.
Cerritos, CA 90703



| IODENT SENSITIVE EXTRA WHITENING | | |
|--|-------------------|--------------------|
| sodium fluoride potassium nitrate paste | | |
| Product Information | | |
| Product Type | HUMAN OTC DRUG | Item Code (Source) |
| Route of Administration | DENTAL | NDC:65923-105 |
| Active Ingredient/Active Moiety | | |
| Ingredient Name | Basis of Strength | Strength |
| SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O) | FLUORIDE ION | 5 mg in 1 g |
| POTASSIUM NITRATE (UNII: RU45X2JN0Z) (NITRATE ION - UNII:T93E9Y2844) | POTASSIUM NITRATE | 2.43 mg in 1 g |
| Inactive Ingredients | | |
| Ingredient Name | Strength | |
| GLYCERIN (UNII: PDC6A3C0OX) | | |
| SODIUM LAURYL SULFATE (UNII: 368GB5141J) | | |
| SORBITOL (UNII: 506T60A25R) | | |
| CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311) | | |
| HYDRATED SILICA (UNII: Y6O7T4G8P9) | | |
| POLYETHYLENE GLYCOL 1500 (UNII: 1212Z7S33A) | | |
| SODIUM PYROPHOSPHATE (UNII: O352864B8Z) | | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | | |

| | |
|--|--|
| SODIUM BENZOATE (UNII: OJ245FE5EU) | |
| METHYL PARABEN (UNII: A2I8C7HI9T) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |
| SACCHARIN SODIUM (UNII: SB8ZUX40TY) | |
| SODIUM PHOSPHATE, TRIBASIC, ANHYDROUS (UNII: SX01TZO3QZ) | |
| PROPYL PARABEN (UNII: Z8IX2SC1OH) | |

Product Characteristics

| | | | |
|-----------------|-------|---------------------|--|
| Color | white | Score | |
| Shape | | Size | |
| Flavor | MINT | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:65923-105-04 | 1 in 1 CARTON | 12/21/2016 | |
| 1 | | 113 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 | 10/23/2014 | |

Labeler - United Exchange Corp. (840130579)