

LUCKY SUPER SOFT WHITENING ANTI CAVITY- sodium monofluorophosphate paste, dentifrice

Delta Brands 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.

Drug Facts

Active Ingredient

Sodium monofluorophosphate 0.76% (Total fluoride content-1000 ppm approx.)

Purpose

Anticavity

Use

regular brushing with fluoride toothpaste helps protect against cavities

Keep out of the reach of children

under 6 years of age

Warnings

In case of accidental overdose, seek professional assistance or contact a Poison Control Center immediately

Directions

adults and children 2 yrs and older brush teeth thoroughly after meals or at least twice a day or use as directed by a dentist or physician. children under 6 yrs to minimize swallowing use a pea-sized amount and brushing until good habits are established. children under 2 years: ask a dentist or physician

Inactive ingredients

calcium carbonate, calcium hydrogen phosphate, carboxymethyl cellulose, FDC Blue 1, flavor, glycerin, hydrated alumina, hydrated silica, potassium sorbate, sodium lauryl sulfate, sodium saccharin, sorbitan monooleate, sorbitol, titanium dioxide, water, xanthan gum

Package Label

| | |
|---|------------------------------|
| Drug Facts | |
| Active ingredient Sodium monofluorophosphate - 0.76% (Total fluoride content - 1000 ppm approx.) | Purpose Anticavity |
| Use regular brushing with fluoride toothpaste helps protect teeth against cavities | |
| Warnings Keep out of the reach of children under 6 years of age. In case of accidental overdose, seek professional assistance or contact a Poison Control Center immediately. | |

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|--|---|
| Drug Facts (continued) | |
| Directions | |
| adults and children 2 yrs, and older | brush teeth thoroughly after meals or at least twice a day or use as directed by a dentist or physician |
| children under 6 yrs | to minimize swallowing use a pea-sized amount and supervise brushing until good habits are established |
| children under 2 yrs | ask a dentist or physician |
| Inactive ingredients calcium carbonate, calcium hydrogen phosphate, carboxymethyl cellulose, FD&C blue#1, flavor, glycerin, hydrated alumina, hydrated silica, potassium sorbate, sodium lauryl sulfate, sodium saccharin, sorbitan monooleate, sorbitol, titanium dioxide, water, xanthan gum | |

11/10/2020

Manufactured for
DELTA BRANDS INC.
Larchmont, NY 10538 USA
www.deltabrands.com
Made in China

ITEM NO: 11197

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LUCKY SUPER SOFT WHITENING ANTI CAVITY

sodium monofluorophosphate paste, dentifrice

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:20276-553 |
| Route of Administration | DENTAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength | | |
|---|--|--|----------------------|--------------------|
| SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O) | FLUORIDE ION | 7.6 mg in 1 g | | |
| Inactive Ingredients | | | | |
| Ingredient Name | Strength | | | |
| POTASSIUM SORBATE (UNII: 1VPU26JZZ4) | | | | |
| CALCIUM CARBONATE (UNII: H0G9379FGK) | | | | |
| ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J) | | | | |
| CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311) | | | | |
| SODIUM SILICATE (UNII: IJF18F77L3) | | | | |
| SODIUM LAURYL SULFATE (UNII: 368GB5141J) | | | | |
| GLYCERIN (UNII: PDC6A3C0OX) | | | | |
| ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0) | | | | |
| HYDRATED SILICA (UNII: Y6O7T4G8P9) | | | | |
| FD&C BLUE NO. 1 (UNII: HBR47K3TBD) | | | | |
| SORBITAN MONOOLEATE (UNII: 06XEA2VD56) | | | | |
| SACCHARIN SODIUM (UNII: SB8ZUX40TY) | | | | |
| SORBITOL (UNII: 506T60A25R) | | | | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | | | | |
| WATER (UNII: 059QF0KO0R) | | | | |
| XANTHAN GUM (UNII: TTV12P4NEE) | | | | |
| Product Characteristics | | | | |
| Color | blue | Score | | |
| Shape | | Size | | |
| Flavor | MINT | Imprint Code | | |
| Contains | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:20276-553-01 | 2 in 1 BOX | 03/31/2017 | |
| 1 | NDC:20276-553-04 | 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 final | part355 | 03/31/2017 | | |

Labeler - Delta Brands Inc (102672008)