NATURE MINT ANTICAVITY- sodium monofluorophosphate paste, dentifrice Daxal Cosmetics Private Limited

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.

Nature Mint Anticavity

ACTIVE INGREDIENT

Sodium Monofluorophosphate - 0.76% (Total Fluoride Content - 1000 ppm Approx.)

DRUG FACTS

PURPOSE

Anticavity.

USE

Helps protect against cavities.

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 immediately.

INACTIVE INGREDIENTS

Calcium Carbonate, Purified Water, Sorbitol, Precipitated Silica, Sodium Lauryl Sulphate, Glycerin, Sodium Carboxy Methyl Cellulose, Flavor, Sodium Saccharin, Sodium Benzoate.

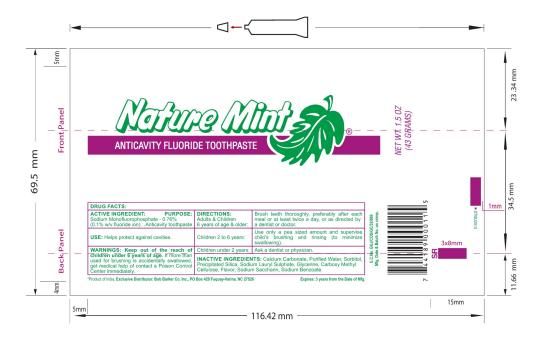
DIRECTIONS:

Adults & Children 6 years of age & older: Brush teeth throughly, preferably after each meal or at least twice a day, or as directed by a dentist or doctor.

Children 2 to 6 years: Use only a pea sized amount and supervise child's brushing and rinsing (to minimize swallowing).

Children under 2 years: Ask a dentist or physician.

PRINCIPAL DISPLAY PANEL - 43 g Tube



NATURE MINT ANTICAVITY

sodium monofluorophosphate paste, dentifrice

| Product Information | | | | |
|-------------------------|----------------|--------------------|---------------|--|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:76001-001 | |
| Route of Administration | DENTAL | | | |

| Active Ingredient/Active Moiety | | | | |
|---|----------------------|--------------------|--|--|
| Ingredient Name | Basis of Strength | Strength | | |
| SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O) | FLUORIDE ION | 0.76 g in 100 g | | |

| Inactive Ingredients | | | |
|--|----------|--|--|
| Ingredient Name | Strength | | |
| GLYCERIN (UNII: PDC6 A3C0 OX) | | | |
| CALCIUM CARBONATE (UNII: H0 G9 379 FGK) | | | |
| WATER (UNII: 059QF0KO0R) | | | |
| SORBITOL (UNII: 506T60A25R) | | | |
| SILICON DIO XIDE (UNII: ETJ7Z6 XBU4) | | | |
| SODIUM LAURYL SULFATE (UNII: 368GB5141J) | | | |
| CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311) | | | |
| SACCHARIN SODIUM (UNII: SB8ZUX40TY) | | | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | | | |
| | | | |

| Product Characteristics | | | | |
|-------------------------|-------|--------------|--|--|
| Color | white | Score | | |
| Shape | | Size | | |
| Flavor | | Imprint Code | | |
| Contains | | | | |

| P | Packaging | | | | | |
|---|------------------|---|-----------------------------|---------------------------|--|--|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date | | |
| 1 | NDC:76001-001-01 | 7.94 g in 1 PACKET; Type 0: Not a Combination Product | 0 1/0 1/20 18 | | | |
| 2 | NDC:76001-001-02 | 17 g in 1 TUBE; Type 0: Not a Combination Product | 0 1/0 1/20 18 | | | |
| 3 | NDC:76001-001-03 | 24 g in 1 TUBE; Type 0: Not a Combination Product | 0 1/0 1/20 18 | | | |
| 4 | NDC:76001-001-04 | 43 g in 1 TUBE; Type 0: Not a Combination Product | 0 1/0 1/20 18 | | | |
| 5 | NDC:76001-001-05 | 78 g in 1 TUBE; Type 0: Not a Combination Product | 0 1/0 1/20 18 | | | |
| 6 | NDC:76001-001-07 | 1 in 1 CARTON | 0 1/0 1/20 18 | | | |
| 6 | | 181 g in 1 TUBE; Type 0: Not a Combination Product | | | | |
| 7 | NDC:76001-001-06 | 1 in 1 CARTON | 0 1/0 1/20 18 | | | |
| 7 | | 130 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 | 0 1/0 1/20 18 | | |
| | | | | |

Labeler - Daxal Cosmetics Private Limited (650497790)

| Establishment | | | | |
|---------------------------------|---------|-----------|-------------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| Daxal Cosmetics Private Limited | | 650497790 | manufacture (76001-001) | |

Revised: 8/2019 Daxal Cosmetics Private Limited