

ANTI CAVITY FLUORIDE- sodium monofluorophosphate paste
Universal Distribution Center LLC

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.

UNIVERSAL ANTI-CAVITY FLUORIDE TOOTHPASTE

Active Ingredient

Sodium Monofluorophosphate 0.76%
(1000 ppm)

Purpose

Anticavity toothpaste

Uses

- regular brushing with fluoride toothpaste helps protect teeth against cavities
- aids in the prevention of dental cavities.

Warning

When using this product

- if pain\ sensitivity still persists after 4 weeks of use, please visit your dentist.

Stop and ask a dentist

- if the problem persists or worsens.

Sensitivity teeth may indicate a serious problem that may need prompt care by a dentist.

Keep out of reach of children under 6 years of age

- If accidentally swallowed get medical help or contact a Poison Control Center right away.

Directions

- adults and children of 2 years and older: brush teeth thoroughly, after meals or at least twice a day, or as directed by a dentist.
- do not swallow.
- to minimize swallowing, use a pea-sized amount in children under 6 years old.
- supervise children's brushing until good habits are established.
- children under 2 years: ask a dentist before use.

Children under 12 years of age: Consult a dentist or doctor

Other information

- store in a cool, dry place.

Inactive Ingredients

Calcium carbonate, Water, Glycerine, Silica, Sodium Lauryl sulphate, Sorbitol, Xanthan gum, Sodium saccharine, Sodium benzoate, Sodium carboxy methyl cellulose and Flavor

PRINCIPAL DISPLAY PANEL

ANTI-CAVITY FLUORIDE TOOTHPASTE



ANTI CAVITY FLUORIDE

sodium monofluorophosphate paste

Product Information

| | | | |
|-------------------------|----------------|--------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:520 00-107 |
| 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 |
|--------------------------------------|----------|
| CALCIUM CARBONATE (UNII: H0G9379FGK) | |
| WATER (UNII: 059QF0KO0R) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |

| SODIUM LAURYL SULFATE (UNII: 368GB5141J) | | | | |
|--------------------------------------------------------------------|------------------|----------------------------------------------------|----------------------|--------------------|
| SORBITOL (UNII: 506T60A25R) | | | | |
| XANTHAN GUM (UNII: TTV12P4NEE) | | | | |
| SACCHARIN SODIUM (UNII: SB8ZUX40TY) | | | | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | | | | |
| CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311) | | | | |
| | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:52000-107-01 | 181 g in 1 TUBE; Type 0: Not a Combination Product | 05/15/2020 | |
| | | | | |
| Marketing Information | | | | |
| Marketing Category | | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph final | | part355 | 05/15/2020 | |
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Labeler - Universal Distribution Center LLC (019180459)

| Establishment | | | |
|----------------------|---------|-----------|------------------------|
| Name | Address | ID/FEI | Business Operations |
| Orchid Lifesciences | | 675474890 | manufacture(52000-107) |