

**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 thoroughly, 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

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:76001-001
<b>Route of Administration</b>	DENTAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>SODIUM MONOFLUOROPHOSPHATE</b> (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.76 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>CALCIUM CARBONATE</b> (UNII: H0G9379FGK)	
<b>WATER</b> (UNII: 059QF0K00R)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM</b> (UNII: K679OBS311)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	

## Product Characteristics

<b>Color</b>	white	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

## 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	01/01/2018	
2	NDC:76001-001-02	17 g in 1 TUBE; Type 0: Not a Combination Product	01/01/2018	
3	NDC:76001-001-03	24 g in 1 TUBE; Type 0: Not a Combination Product	01/01/2018	
4	NDC:76001-001-04	43 g in 1 TUBE; Type 0: Not a Combination Product	01/01/2018	
5	NDC:76001-001-05	78 g in 1 TUBE; Type 0: Not a Combination Product	01/01/2018	
6	NDC:76001-001-07	1 in 1 CARTON	01/01/2018	
6		181 g in 1 TUBE; Type 0: Not a Combination Product		
7	NDC:76001-001-06	1 in 1 CARTON	01/01/2018	
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	01/01/2018	

**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