# IODENT FLUORIDE MINT-sodium monofluorophosphate paste, dentifrice Dabur India 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.

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### **Drug Facts**

### **Active Ingredient**

Sodium Monofluorophospate 0.76% (Total Fluoride Content – 1000 ppm Approx.)

#### **Purpose**

Anticavity

#### Uses

Regular brushing with Fluoride toothpaste helps protect teeth and roots against cavities

### **Warnings**

#### Keep out of reach of children under 6 years of age.

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

Directions	
Adults and children	Brush teeth thoroughly after meals or at least twice a day or use as
2 years and older	directed by a dentist or physician.
Children under 6 yrs To minimize swallowing use a pea-sized amount and supervise brushin	
	until good habits are established.
Children under 2 yrs	Ask a dentist or physician.

#### **Ingredients**

Calcium Carbonate, Water, Sorbitol, Precipitated Silica, Sodium Lauryl sulphate, Flavor, Sodium Carboxy Methyl Cellulose, Sodium Silicate, Tetra Sodium Pyrophosphate, Sodium Saccharin, Methyl Paraben, Titanium Dioxide, Poly Ethylene Glycol 400, Propyl Paraben.

Principal Display Panel – Carton Label

IODENT® CAVITY FIGHTING TOOTHPASTE FLUORIDE Mint Flavor CAVITY PROTECTION & EXTRA BREATH FRESHENING NET WT 6.4 OZ (181g)



Principal Display Panel – Tube Label

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Made in India C.No. DNH/COS/DNH/52

#### **IODENT FLUORIDE MINT**

sodium monofluorophosphate paste, dentifrice

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:68747-6032

Route of Administration DENTAL

### Active Ingredient/Active Moiety

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I	Ingredient Name	Basis of Strength	Strength		
I	<b>SODIUM MONOFLUOROPHOSPHATE</b> (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80 VPU408O)	SODIUM MONOFLUOROPHOSPHATE	7.6 mg in 1 g		

## **Inactive Ingredients**

Ingredient Name	Strength
CALCIUM CARBONATE (UNII: H0 G9 379 FGK)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
CARBO XYMETHYLCELLULOSE SODIUM (UNII: K679 OBS 311)	
SODIUM PYROPHOSPHATE (UNII: O352864B8Z)	
SACCHARIN SO DIUM (UNII: SB8 ZUX40 TY)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	
METHYLPARABEN (UNII: A2I8 C7HI9 T)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

Product Characteristics				
Color		Score		
Shape		Size		
Flavor	MINT (MINT)	Imprint Code		
Contains				

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68747-6032-1	1 in 1 CARTON		
1		181 g in 1 TUBE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	02/28/2012	

# Labeler - Dabur India Limited (650319218)

Establishment				
Name	Address	ID/FEI	Business Operations	
Dabur India Limited		650319218	MANUFACTURE	

Revised: 8/2008 Dabur India Limited