IODENT FLUORIDE TOOTHPASTE- fluoride toothpaste 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.

Iodent Fluoride Toothpaste

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 and roots against cavities

WARNING

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.

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.

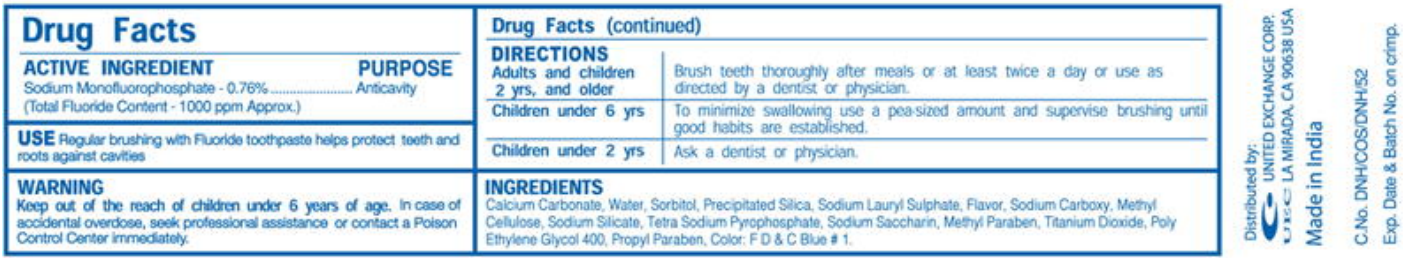
INGREDIENTS

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, Color: F D & C Blue # 1.

Fluoride Toothpaste Tube Label
FREE
Toothbrush
IODENT™
CAVITY FIGHTING TOOTHPASTE
Fluoride
CAVITY PROTECTION & EXTRA RREATH FRESHENING
NET WT 6.4 OZ(181g)

CAVITY PROTECION

Regular Flavor



Fluoride Toothpaste Carton Label
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IODENT FLUORIDE TOOTHPASTE

fluoride toothpaste paste, dentifrice

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68747-6029
Route of Administration	DENTAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)	SODIUM MONOFLUOROPHOSPHATE	7.6 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
CALCIUM CARBONATE (UNII: H0G9379FGK)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	

CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
SODIUM SILICATE (UNII: IJF18F77L3)	
SODIUM PYROPHOSPHATE (UNII: O352864B8Z)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	MINT (MINT)	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68747-6029-1	181 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	08/25/2009	

Labeler - Dabur India Limited (650319218)

Establishment

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

Revised: 8/2008 Dabur India Limited