FRESHENUP FLUORIDE DOUBLE MINT- sodium monofluorophosphate paste, dentifrice
U. S. Nonwovens Corp

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.

Freshenup 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 against cavities

Warnings

Keep out of the reach of children

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 right away.

Directions

adults and children 2 years 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 years	to minimize swallowing use a pea sized amount and supervise brushing until good habits are established
children under 2 years	ask a dentist or physician

Inactive ingredients

Calcium Carbonate, Sorbitol, Aqua, Silica, Sodium Lauryl Sulphate, Flavour, Sodium Silicate, Tetra Sodium Pyrophosphate, Cellulose Gum, Xanthan Gum, Benzyl Alcohol, Sodium Saccharin, Sodium Benzoate, Zinc Gluconate

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PRINCIPAL DISPLAY PANEL

NDC 52553-049-02

ANTICAVITY

Freshenup

FLUORIDE TOOTHPASTE

DOUBLE MINT

SENSITIVE + GENTLE

BREATH DETOX

Bacteria + Germs

Fight Gengivitis

Gum Scrub™ - Fight Gum Building

NET WT 3.5 OZ (99.2 g)

FRESHENUP FLUORIDE DOUBLE MINT

sodium monofluorophosphate paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:52553-049
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Sodium Monofluorophosphate (UNII: C810JCZ56Q) (fluoride ion - UNII:Q80VPU408O)	fluoride ion	7.6 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
CALCIUM CARBONATE (UNII: H0G9379FGK)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM SILICATE (UNII: IJF18F77L3)	
SODIUM PYROPHOSPHATE (UNII: O352864B8Z)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
XANTHAN GUM (UNII: TTV12P4NEE)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
ZINC GLUCONATE (UNII: U6WSN5SQ1Z)	

Product Characteristics

Color	WHITE	**Score**	
Shape		**Size**	
Flavor	MINT	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52553-049-02	1 in 1 CARTON	08/14/2019	
1		99.2 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 not final	part356	08/14/2019	

Labeler - U. S. Nonwovens Corp (847061520)

Registrant - U. S. Nonwovens Corp (847061520)

Establishment

Name	Address	ID/FEI	Business Operations
Dabur India Limited		650599231	manufacture(52553-049)

Revised: 8/2019

U. S. Nonwovens Corp