REMBRANDT- sodium monofluorophosphate paste, dentifrice
Ashtel Studios, Inc

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.

REMBRANDT® TOOTHPASTE WITH FLUORIDE

Drug Facts

Active Ingredient: Sodium Monofluorophosphate 0.76%

Purpose: Anticavity

Use: Aids in the prevention of dental cavities.

Warnings: Keep out of reach of children under 6 years of age. If more than amount used for brushing is accidentally swallowed,
seek medical help or contact a Poison Control Center right away.

Directions: Adults and children 2 years of age & older: Brush teeth thoroughly after meals or at least twice a day or use as directed by a dentist. Do not swallow. **Children under 6 years of age:** Use a pea-sized amount and instruct in good brushing and rinsing habits (to minimize swallowing). Supervise children as necessary until capable of using without supervision. **Children under 2 years of age:** Consult a dentist or doctor. Do not swallow.

Inactive ingredients: CALCIUM CARBONATE, SORBITOL, TREATED WATER, SILICA, SODIUM LAURYL SULPHATE, FLAVOR, SODIUM CARBOXY METHYL CELLULOSE, SODIUM SILICATE, TETRA SODIUM PYROPHOSPHATE, BENZYL ALCOHOL, SODIUM SACCHARIN, PROPYLPARABEN.

 MADE IN INDIA
DIST. BY: ASHTEL STUDIOS, INC., ONTARIO, CA 91761 • **COMMENTS OR QUESTIONS?**
1-877-274-8358 TOLL FREE IN U.S.A. • 1-909-434-0911 INTERNATIONAL

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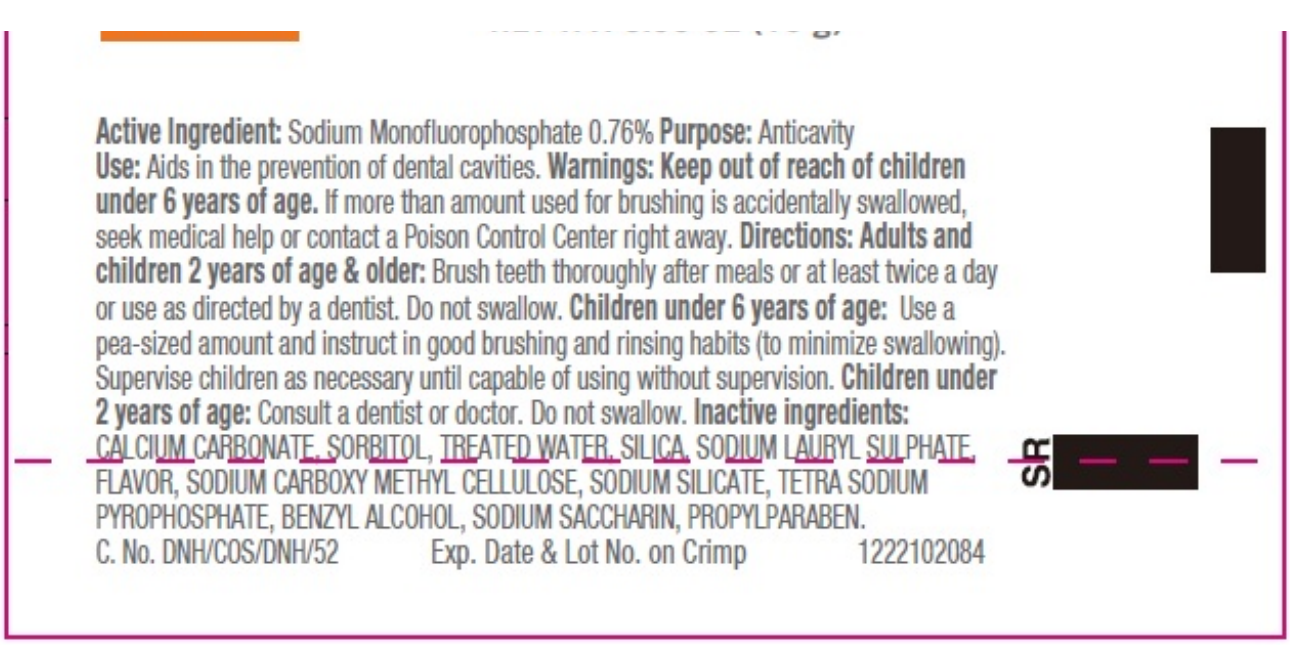
QUICK CLEAN®

TOOTHPASTE WITH FLUORIDE

Packaging



REMBRANDT

sodium monofluorophosphate paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70108-031
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)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
SODIUM SILICATE (UNII: IJF18F77L3)	
SODIUM PYROPHOSPHATE (UNII: O352864B8Z)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70108-031-01	10 g in 1 TUBE; Type 0: Not a Combination Product	12/15/2019	
2	NDC:70108-031-02	20 g in 1 TUBE; Type 0: Not a Combination Product	12/15/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	12/15/2019	

Labeler - Ashtel Studios, Inc (148689180)

Revised: 12/2019 Ashtel Studios, Inc