

MORNING FRESH- sodium monofluorophosphate paste
Choice Laboratories 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.

Toothpaste

Active Ingredient

Sodium Monofluorophosphate 0.76 %

Purpose: Anticavity

Use

- Aids in the prevention of dental cavities.

Inactive Ingredient

Calcium carbonate, Carboxymethylcellulose sodium, Flavour, Hydrated silica, Purified water, Saccharin sodium, Sodium benzoate, Sodium lauryl sulfate, Sorbitol

Dosage and Administration

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.*

Indications and Usage

- The prevention of dental cavities.

Warnings

- If you accidentally swallow more than used for brushing, seek professional assistance or contact a Poison Control Center immediately.

Keep out of reach of children.

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

Principal Display Panel

Choice Laboratories Ltd

Toothpaste

Choice Ver Toothpaste.jpg

Reorder No. 4873

Net Wt. 2.75 oz (78g)

NDC# 63174-171-02

N. C. No: DD/COS/DD/C/340



Global Choice for complete personal care

Manufactured by:

Choice Laboratories Limited

Ahmedabad, Gujarat 384215, India

Flouride Toothpaste

Made in India

 <p>FOR BEST RESULTS, SQUEEZE TUBE FROM THE BOTTOM AND FLATTEN AS YOU GO UP.</p> <p>Batch No. and Expiration Date are on the crimp</p>	<p>Drug Facts</p> <p>Active Ingredient Purpose Sodium Monofluorophosphate 0.76% (0.1% w/v Fluoride Ion) Anticavity</p> <p>Use Aids in the prevention of dental cavities.</p> <p>Warnings <i>Keep out of reach of children under 6 years of age</i></p> <p>• If you accidentally swallow more than used for brushing seek professional assistance or contact a Poison Control Center immediately.</p>	<p>Drug Facts (continued)</p> <p>Directions <i>Adults and children 2 yrs. and older</i> • Brush teeth thoroughly after meals or at least twice a day or use as directed by a dentist or physician. <i>Children under 6 yrs.</i> • To minimize swallowing use a pea sized amount and supervise brushing until good habits are established. <i>Children under 2 yrs.</i> • Ask a dentist or physician.</p> <p>Inactive Ingredients • Calcium carbonate, Carboxymethylcellulose sodium, Flavor, Hydrated silica, Purified water, Saccharin sodium, Sodium benzoate, Sodium lauryl sulfate, Sorbitol.</p>
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MORNING FRESH

sodium monofluorophosphate paste

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63174-172
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
SORBITOL (UNII: 506T60A25R)	
HYDRATED SILICA (UNII: Y607T4G8P9)	
CALCIUM CARBONATE (UNII: H0G9379FGK)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
WATER (UNII: 059QF0KO0R)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63174-172-01	43 g in 1 TUBE		
2	NDC:63174-172-02	78 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	04/05/2013	

Labeler - Choice Laboratories Limited (650070394)

Revised: 4/2013

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