

MORNING FRESH- sodium fluoride paste
Dynarex Corporation

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.

4872 Morning Fresh Toothpaste NDC 67777-175-01

4873 Morning Fresh Toothpaste NDC 67777-175-02

Active Ingredient

Sodium Monofluorophosphate 0.76 %

Purpose: Anticavity

Use

- Aids in the prevention of dental cavities.

Inactive Ingredient

Calcium carbonate, Carboxymethylcellulose sodium, Flavour, Methylparaben, Polyethylene glycol 400, Propylparaben, Saccharin sodium, Silicon dioxide, Sodium benzoate, Sodium lauryl sulphate, Sodium pyrophosphate, Sodium silicate, Sorbitol, Titanium dioxide, Water

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

Dynarex Morning Fresh Toothpaste

Morning Fresh.jpg

Reorder No. 4873
Net Wt. 2.75 oz (78g)

NDC# 67777-175-02
 C. No. DNH/COS/DNH/52

Morning Fresh
 Fluoride Toothpaste



Manufactured for:
 Dynarex Corporation
 Orangeburg, NY 10962
 www.dynarex.com

Made in India

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 16784 48731
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FOR BEST RESULTS, SQUEEZE TUBE FROM THE BOTTOM AND FLATTEN AS YOU GO UP.

Lot No. and Expiration Date are on the crimp

Drug Facts		Drug Facts (continued)
Active Ingredient Sodium Monofluorophosphate - 0.76%..... (Total Fluoride Content 1000 ppm Approx.)	Purpose Anticavity	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.
Use Aids in the prevention of dental cavities.		
Warnings Keep out of reach of children under 6 years of age • If you accidentally swallow more than used for brushing seek professional assistance or contact a Poison Control Center immediately.		Inactive Ingredients • Calcium carbonate, Carboxymethylcellulose sodium, Flavor, Methylparaben, Polyethylene glycol 400, Propylparaben, Saccharin sodium, Silicon dioxide, Sodium benzoate, Sodium lauryl sulphate, Sodium pyrophosphate, Sodium silicate, Sorbitol, Titanium dioxide, Water.

MORNING FRESH

sodium fluoride paste

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67777-175
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	76 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
SORBITOL (UNII: 506T60A25R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
WATER (UNII: 059QF0KO0R)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM SILICATE (UNII: IJF18F77L3)	
SODIUM PYROPHOSPHATE (UNII: O352864B8Z)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
CALCIUM CARBONATE (UNII: H0G9379FGK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67777-175-11	144 in 1 CASE	10/14/2014	
1	NDC:67777-175-10	1 in 1 BOX		
1	NDC:67777-175-01	43 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:67777-175-13	144 in 1 CASE	10/14/2014	
2	NDC:67777-175-12	1 in 1 BOX		
2	NDC:67777-175-02	78 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 final	part355	10/14/2014	

Labeler - Dynarex Corporation (008124539)

Registrant - Dynarex Corporation (008124539)