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.

Toothpaste

Active Ingredient

Sodium Fluoride 0.22 %

Purpose: Anticavity

Use

- Aids in the prevention of dental cavities.

Inactive Ingredient

Calcium carbonate, Carboxymethycellulose sodium, Flavour, Hydrated silica,Potassium nitrate, 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

Dynarex Morning Fresh Toothpaste

Morning Fresh.jpg

MORNING FRESH

sodium fluoride paste

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:67777-174
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	2.2 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
SORBITOL (UNII: 506T60A25R)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
CALCIUM CARBONATE (UNII: H0G9379FGK)	

SODIUM BENZOATE (UNII: OJ245FE5EU)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
WATER (UNII: 059QF0KO0R)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
POTASSIUM NITRATE (UNII: RU45X2JN0Z)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67777-174-01	43 g in 1 TUBE		
2	NDC:67777-174-02	78 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	05/14/2014	

Labeler - Dynarex Corporation (008124539)

Registrant - Dynarex Corporation (008124539)

Revised: 5/2014 Dynarex Corporation