

## **MORNING FRESH- sodium monofluorophosphate 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.*

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### **Toothpaste**

#### **Active Ingredient**

Sodium Monofluorophosphate 0.76 %

#### **Purpose: Anticavity**

##### **Use**

- Aids in the prevention of dental cavities.

#### **Inactive Ingredient**

Calcium carbonate, Carboxymethylcellulose sodium, Flavour, Methylparaben sodium, Propylparaben sodium, Purified water, Saccharin sodium, Silicon dioxide, 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**

Toothpaste.jpg

Net Wt. 1.5 OZ (43g)  
 Reorder No. 4872

NDC #67777-171-01  
 N. C. No: DD/COS/DD/C/340

**Morning  
 Fresh**



Flouride Toothpaste

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

Made in India



<b>Drug Facts</b>	
<b>Active Ingredient</b> .....	<b>Purpose</b>
Sodium Monofluorophosphate 0.76% (0.1% w/V Fluoride ion).....	Anticavity
<b>Use</b>	
Aids in the prevention of dental cavities.	
<b>Warnings</b>	
<b>Keep out of reach of children under 6 years of age</b>	
<ul style="list-style-type: none"> <li>if you accidentally swallow more than used for brushing seek professional assistance or contact a Poison Control Center immediately.</li> </ul>	

<b>Drug Facts (continued)</b>
<b>Directions</b>
<b>Adults and children 2 yrs. and older</b> • Brush teeth thoroughly after meals or at least twice a day or use as directed by a dentist or physician.
<b>Children under 6 yrs.</b> • To minimize swallowing use a pea sized amount and supervise brushing until good habits are established.
<b>Children under 2 yrs.</b> • Ask a dentist or physician.
<b>Inactive Ingredients</b> • Sorbitol, Silicon Dioxide, Calcium Carbonate, Methylparaben Sodium, Propylparaben Sodium, Flavour, Saccharin Sodium, Purified Water, Carboxymethylcellulose Sodium, Sodium Lauryl Sulfate.

<b>MORNING FRESH</b>			
sodium monofluorophosphate paste			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:67777-171
<b>Route of Administration</b>	ORAL		
<b>Active Ingredient/Active Moiety</b>			
	<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
	SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	1 mg in 1 g
<b>Inactive Ingredients</b>			
	<b>Ingredient Name</b>		<b>Strength</b>
	SORBITOL (UNII: 506T60A25R)		
	SILICON DIOXIDE (UNII: ETJ7Z6XBU4)		
	CALCIUM CARBONATE (UNII: H0G9379FGK)		
	METHYLPARABEN SODIUM (UNII: CR6K9C2NHK)		
	PROPYLPARABEN SODIUM (UNII: 625NNB0G9N)		
	SACCHARIN SODIUM (UNII: SB8ZUX40TY)		

<b>WATER</b> (UNII: 059QF0KO0R)	
<b>CARBOXYMETHYLCELLULOSE SODIUM</b> (UNII: K679OBS311)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67777-171-01	43 g in 1 TUBE		
2	NDC:67777-171-02	78 g in 1 TUBE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	06/08/2010	

**Labeler** - Dynarex Corporation (008124539)

**Registrant** - Dynarex Corporation (008124539)