

**REGULAR - sodium monofluorophosphate paste, dentifrice**  
**Kareway Product, 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.*

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**Drug Facts**

**Active ingredient**

Sodium Monofluorophosphate 0.76% (0.15%w/v fluoride ion)

**Purpose**

Anticavity

**Usage**

helps protect against cavities

**Warnings**

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

If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

**Directions**

Adults and children 2 years of age and older	brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or physician
Children 2 to 6 years	use only a pea sized amount and supervise child's brushing and rinsing (to minimize swallowing).
Children under 2 years	ask a dentist or physician

**Inactive ingredients**

calcium carbonate, sorbitol, water, silicon dioxide, glycerine, sodium lauryl sulfate, sodium carboxymethyl cellulose, methyl parahydroxybenzoate, aminocaproic acid, xylitol, sodium saccharin, DL-menthol, flavor

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## REGULAR

sodium monofluorophosphate paste, dentifrice

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67510-0012
Route of Administration	DENTAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)	SODIUM MONOFLUOROPHOSPHATE	0.76 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
CALCIUM CARBONATE (UNII: H0G9379FGK)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0K00R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
GLYCERIN (UNII: PDC6A3C0OX)	

<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>CARBOXYMETHYLCELLULOSE SODIUM</b> (UNII: K679OBS311)	
<b>METHYL PARABEN</b> (UNII: A218C7H9T)	
<b>AMINOCAPROIC ACID</b> (UNII: U6F3787206)	
<b>XYLITOL</b> (UNII: VCQ006KQ1E)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>MENTHOL</b> (UNII: L7T10EIP3A)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: HBR47K3TBD)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67510-0012-4	1 in 1 BOX		
1		181 g in 1 TUBE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	08/15/2011	

**Labeler** - Kareway Product, Inc. (121840057)

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Kareway Product, Inc.