# MINT - 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

Enter section text here

# 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	brush teeth thoroughly, preferably after each meal or at least twice a day,
of age and older	or as directed by a dentist or physician
If hildren I to 6 vears	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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## **MINT**

sodium monofluorophosphate paste, dentifrice

## **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:67510-0011

Route of Administration DENTAL

#### **Active Ingredient/Active Moiety**

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	Ingredient Name	Basis of Strength	Strength
SODIUM MONOFLUORO UNII:Q80VPU408O)	PHO SPHATE (UNII: C8 10 JCZ56Q) (FLUORIDE ION -	SODIUM MONOFLUOROPHOSPHATE	0.76 g in 100 g

Inactive Ingredients		
Ingredient Name	Strength	
CALCIUM CARBO NATE (UNII: H0 G9 379 FGK)		
SORBITOL (UNII: 506T60A25R)		
WATER (UNII: 059QF0KO0R)		
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)		
GLYCERIN (UNII: PDC6 A3C0 OX)		

SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679 OBS 311)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
AMINO CAPRO IC ACID (UNII: U6F3787206)	
XYLITOL (UNII: VCQ006KQ1E)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
MENTHOL (UNII: L7T10EIP3A)	

Pa	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:67510-0011-4	1 in 1 BOX			
1		181 g in 1 TUBE			
2	NDC:67510-0011-6	1 in 1 BOX			
2		170 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)

Revised: 2/2012 Kareway Product, Inc.