

**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.

Pure-Aid Fluoride Toothpaste Great Regular

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 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

Enter section text here



Regular brushing with Kareway Fluoride toothpaste helps prevent cavities while leaving your mouth feeling fresh and clean

Drug Facts	Purpose	Directions
Active ingredient Sodium Monofluorophosphate 0.76% (0.15%w/w fluoride ion)	Anticavity	Adults and children 2 years and older brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or physician.
Uses helps protect against cavities		Children 2 to 6 years use only a pea sized amount and supervise child's brushing and rinsing to minimize swallowing.
Warnings 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.		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, FD&C blue no 1, flavor



Fluoride **Great Regular Flavor** **KAREWAY**
 Exclusively distributed by:
 Kareway Product Inc. Gardena, CA 90248
 Made in Korea
 NET WT 6.4 OZ (181g)

REGULAR

sodium monofluorophosphate paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67510-0112
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU4080)	FLUORIDE ION	0.76 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CALCIUM CARBONATE (UNII: H0G9379FGK)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
AMINOCAPROIC ACID (UNII: U6F3787206)	
XYLITOL (UNII: VCQ006KQ1E)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
MENTHOL (UNII: L7T10EIP3A)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67510-0112-4	1 in 1 BOX	08/15/2011	
1		181 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	08/15/2011	

Labeler - Kareway Product, Inc. (121840057)

Revised: 2/2023

Kareway Product, Inc.