

AMAR REGULAR- sodium monofluorophosphate paste, dentifrice
Amar Remedies Limited - Mumbai

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.

Amar
REGULAR
Fluoride Toothpaste

DRUG FACTS

Active ingredient

Sodium monofluorophosphate 0.76% (0.1 w/v fluoride ion)

Purpose

Anticavity

Use

helps protect against cavities.

Warning

Keep out of the 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 6 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 a 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

Sorbitol, SCMC, Treated Water, Silica, Sodium Lauryl Sulphate, Flavor, Calcium Carbonate, Sodium Saccharine, Sodium Methyl Paraben, Sodium Propyl Paraben.

Distributed by: Amar Remedies Inc.

PRINCIPAL DISPLAY PANEL - 181 g Carton

NEW

Anticavity Fluoride Toothpaste

Amar

FREE TOOTHBRUSH

REGULAR

Toothpaste

Anticavity Fluoride Toothpaste



AMAR REGULAR

sodium monofluorophosphate paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41499-106
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Sodium monofluorophosphate (UNII: C8 10JCZ56Q) (Fluoride Ion -	Sodium	0.76 g

UNII:Q80VPU408O)	mono fluoro phosphate	in 100 g		
Inactive Ingredients				
Ingredient Name		Strength		
Water (UNII: 059QF0KO0R)				
Silicon Dioxide (UNII: ETJ7Z6XBU4)				
Product Characteristics				
Color	WHITE	Score		
Shape		Size		
Flavor	MINT	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41499-106-01	181 g in 1 TUBE		
2	NDC:41499-106-02	181 g in 1 TUBE		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH FINAL	part355	12/01/2009		

Labeler - Amar Remedies Limited - Mumbai (677141751)

Revised: 12/2009

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