AP-24 FLUORIDE- sodium monofluorophosphate paste NSE Products, 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.

AP-24_® Fluoride Toothpaste

Drug Facts

Active Ingredients

Sodium Monofluorophosphate 0.86% (0.15% w/v fluoride ion)

Purpose

anticavity

Use

Aids in the prevention of dental 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 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 doctor.
- Instruct children under 6 years of age in good brushing and rinsing habits (to minimize swallowing).
- Supervise children as necessary until capable of using without supervision.
- Children under 2 years of age: Consult a dentist or doctor.

Inactive Ingredients

Dicalcium Phosphate Dihydrate, Water (Aqua), Sorbitol, Glycerin, Dimethicone, Poloxamer 338, Poloxamer 407, Cellulose Gum, Sodium Lauryl Sulfate, Flavor (Aroma), Sodium Saccharin, Titanium Dioxide (CI 77891).

Questions?

1-888-742-7626

PRINCIPAL DISPLAY PANEL - 170 g Tube Label

AP24®

Anti-Plaque

¹ AP-24, [®] the patented ultra-emulsion of medical grade, high molecular weight Dimethicone and the surfactants Poloxamer 338 and Poloxamer 407, helps to remove plaque during brushing and helps reduce plaque buildup.

Fluoride Toothpaste

NU SKIN®

170 g e (6 OZ.)



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Sold Exclusively by Nu Skin Enterprises Authorized Distributors

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AP-24 FLUORIDE

sodium monofluorophosphate paste

P	roc	luct	Information
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Product Type HUMAN OTC DRUG Item Code (Source) NDC:62839-1151

Route of Administration DENTAL

ı	Active Ingredient/Active Moiety		
	Ingredient Name	Basis of Strength	Strength
	SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	8.6 mg in 1 g

Inactive Ingredients		
Ingredient Name	Strength	
DIBASIC CALCIUM PHO SPHATE DIHYDRATE (UNII: O7TSZ97GEP)		
Water (UNII: 059QF0KO0R)		
Sorbitol (UNII: 506T60A25R)		
Dimethicone (UNII: 92RU3N3Y1O)		
Poloxamer 338 (UNII: F75JV2T505)		
Poloxamer 407 (UNII: TUF2IVW3M2)		
Glycerin (UNII: PDC6A3C0OX)		
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)		
Sodium Lauryl Sulfate (UNII: 368GB5141J)		
SACCHARIN SO DIUM (UNII: SB8 ZUX40 TY)		
Titanium Dioxide (UNII: 15FIX9V2JP)		

l	Packaging						
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date			
l	1 NDC:62839-1151-1	170 g in 1 TUBE; Type 0: Not a Combination Product	05/08/2017				

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH FINAL	part355	05/08/2017		

Labeler - NSE Products, Inc. (803486393)

Revised: 5/2017 NSE Products, Inc.