

AP-24 WHITENING- 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® Whitening Toothpaste

Drug Facts

Active Ingredients

Sodium Monofluorophosphate 0.76% (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 immediately.

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 on 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

Water (Aqua), Hydrated Silica, Sorbitol, Alumina, Glycerin, Tetrasodium Pyrophosphate, PEG-12, Dimethicone¹, Poloxamer 338¹, Poloxamer 407¹, Cellulose Gum, Sodium Lauryl Sulfate, Flavor (Aroma), Sodium Saccharin, Titanium Dioxide (CI 77891).

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.

Questions

1-888-742-7626

PRINCIPAL DISPLAY PANEL - 110 g Tube Label

AP24®

Whitening

Fluoride
Toothpaste

NU SKIN®

110 g e (4 oz.)



AP₂₄®

Whitening
Fluoride
Toothpaste



NU SKIN®
110 g e (4 oz.)

Drug Facts

Active Ingredients	Purpose
Sodium Monofluorophosphate 0.76% (0.15% w/v fluoride ion)	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 immediately.

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 on 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: Water (Aqua), Hydrated Silica, Sorbitol, Aluminum Hydroxide, Glycerin, Tetrasodium Pyrophosphate, PEG-12, Dimethicone*, Poloxamer 338*, Poloxamer 407*, Cellulose Gum, Sodium Lauryl Sulfate, Flavor (Aroma), Sodium Saccharin, Titanium Dioxide (CI 77891).

Questions: 1-888-742-7626

**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.*

Sold Exclusively by
Nu Skin Enterprises
Authorized Distributors

Mfd. in the U.S.A. exclusively for
NSE Products, Inc., Provo, UT 84601
©1997, 17 NSE Products, Inc.
nuskin.com
01 111155 90016033/7



sodium monofluorophosphate paste

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62839-1155
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Sodium Monofluorophosphate (UNII: C810JCZ56Q) (Fluoride Ion - UNII:Q80VPU408O)	Fluoride Ion	7.6 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Hydrated Silica (UNII: Y6O7T4G8P9)	
Sorbitol (UNII: 506T60A25R)	
Aluminum Hydroxide (UNII: 5QB0T2IUN0)	
Glycerin (UNII: PDC6A3C0OX)	
Sodium Pyrophosphate (UNII: O352864B8Z)	
Polyethylene Glycol 600 (UNII: NL4J9F21N9)	
Dimethicone (UNII: 92RU3N3Y1O)	
Poloxamer 338 (UNII: F75JV2T505)	
Poloxamer 407 (UNII: TUF2IVW3M2)	
Carboxymethylcellulose Sodium, Unspecified Form (UNII: K679OBS311)	
Sodium Lauryl Sulfate (UNII: 368GB5141J)	
Saccharin Sodium (UNII: SB8ZUX40TY)	
Titanium Dioxide (UNII: 15FIX9V2JP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62839-1155-1	110 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: 10/2017

NSE Products, Inc.