

AP-24- sodium fluoride mouthwash
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® Mouthwash

Drug Facts

Active Ingredient

Sodium Fluoride 0.02% (0.01% w/v fluoride ion)

Purpose

anticavity

Use

Aids in the prevention of dental cavities.

Warning

- **Keep out of the reach of children.** If more than used for rinsing is accidentally swallowed, get medical help or contact a Poison Control Center right away.
- **Do not use if safety seal is broken.**

Directions

- Adults and children 6 years of age and older: Use once a day after brushing your teeth with a toothpaste.
- Vigorously swish 10 milliliters of rinse between your teeth for 1 minute and then spit out.
- Do not swallow the rinse.
- Do not eat or drink for 30 minutes after rinsing.
- Instruct children under 12 years of age in good rinsing habits (to minimize swallowing).
- Supervise children as necessary until capable of using without supervision.
- Children under 6 years of age: Consult a dentist or doctor.

Inactive Ingredients

Water (Aqua), Sorbitol, Glycerin, Poloxamer 338,¹ Poloxamer 407,¹ Dimethicone,¹ Sodium Phosphate, Phosphoric Acid, Disodium EDTA, Sodium Saccharin, Sodium Benzoate, Flavor (Aroma).

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 and helps reduce plaque buildup.

Questions?

1-888-742-7626

PRINCIPAL DISPLAY PANEL - 500 ml Bottle Label

AP24®

Anti-Plaque

Fluoride

Mouthwash

NU SKIN®

500 ml e (16.9 Fl. Oz.)

AP²⁴®

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**Sold Exclusively by Nu Skin Enterprises
Authorized Distributors**

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AP-24

sodium fluoride mouthwash

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62839-1152
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Sodium Fluoride (UNII: 8ZYQ1474W7) (Fluoride Ion - UNII:Q80VPU408O)	Fluoride Ion	0.2 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Sorbitol (UNII: 506T60A25R)	
Glycerin (UNII: PDC6A3C0OX)	
Poloxamer 338 (UNII: F75JV2T505)	
Poloxamer 407 (UNII: TUF2IVW3M2)	
Dimethicone (UNII: 92RU3N3Y1O)	
Sodium Phosphate (UNII: SE337SVY37)	
Phosphoric Acid (UNII: E4GA8884NN)	
Edetate Disodium Anhydrous (UNII: 8NLQ36F6MM)	
Saccharin Sodium (UNII: SB8ZUX40TY)	
Sodium Benzoate (UNII: OJ245FE5EU)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62839-1152-1	500 mL in 1 BOTTLE; 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.