HYVEE ANTICAVITY MINT- sodium fluoride liquid HYVEE 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.

DRUG FACTS

Active ingredient

Sodium Fluoride 0.05% (0.02% w/v Fluoride ion)

Purpose

Antigingivitis/Antiplaque

Uses

aids in the prevention of dental cavities

Warnings

Keep out of reach of children

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If more than used for rinsin is accidentally swallowed, get medical help or contact a Poison Control Center immediately.

Directions

- ||Adults and children 6 years of age and older:
- Iuse once a day after brushing your teeth with toothpaste
- vigorously swish 10 mL 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
- supervise children as necessary until capable of using without supervision
- Children under 6 years of age: consult a dentist or doctor.

Other information

- Store at room temperature
- Cold weather may cloud this product. Its antiseptic properties are not affected.

Inactive ingredients

Calcium Disodium EDTA, Cetylpyridinium Chloride, Disodium Phosphate, Flavor, Green 3 (CI 42053), Menthol, Methyl Salicylate, Poloxamer 407, Polysorbate 20, Potassium Sorbate, Propylene Glycol, Sodium Benzoate, Sodium Phosphate, Sodium Saccharin, Sorbitol, Water (Aqua), Yellow 5 (CI 19140).

Questions or comments?



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Questions or comments? 1-800-289-8343

DO NOT USE IF PRINTED BAND AROUND CAP IS BROKEN OR MISSING.

TO OPEN: SQUEEZE SMOOTH AREAS ON CAP AND TURN. TO CLOSE: TURN CAP UNTIL IT LOCKS.

> DISTRIBUTED BY HY-VEE, INC. WEST DES MOINES, IA 50266

> > MADE IN CANADA

SATISFACTION GUARANTEED CALL 1-800-289-8343 www.hy-vee.com

*This product is not manufactured or distributed by Chattem, Inc., owner of the registered trademark Act®.



HYVEE ANTICAVITY MINT

sodium fluoride liquid

Product Information

Product Type HUMAN OTC DRUG

Item Code (Source)

NDC:42507-554

Route of Administration

ORAL

Active Ingredient/Active Moiety

20569

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.5 mg in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SO DIUM PHO SPHATE (UNII: SE337SVY37)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
SO DIUM BENZO ATE (UNII: OJ245FE5EU)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
EDETATE CALCIUM DISO DIUM ANHYDRO US (UNII: 8 U5D0 349 55)	
SO DIUM PHO SPHATE, DIBASIC, ANHYDRO US (UNII: 22ADO 53M6 F)	
SACCHARIN SO DIUM (UNII: SB8 ZUX40 TY)	
CETYLPYRIDINIUM CHLORIDE (UNII: D9 OM4SK49 P)	
MENTHOL (UNII: L7T10EIP3A)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

l	P	ackaging			
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:42507-554- 17	473 mL in 1 BOTTLE, PLASTIC; 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	11/29/2015		

Labeler - HYVEE INC. (006925671)

Registrant - APOLLO HEALTH AND BEAUTY CARE (201901209)

Establishment				
Name	Address	ID/FEI	Business Operations	
APOLLO HEALTH AND BEAUTY CARE		201901209	manufacture(42507-554)	

Revised: 11/2015 HYVEE INC.