SMART SENSE ANTICAVITY- sodium fluoride liquid KMART CORPORATION

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 0.02% (0.01% W/V FLUORIDE ION)

PURPOSE

ANTICAVITY

USES

AIDS IN THE PREVENTION OF DENTAL CAVITIES.

WARNINGS

KEEP OUT OF REACH OF CHILDREN. IF MORE THAN USED FOR RINSING IS ACCIDENTALLY SWALLOWED, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER IMMEDIATELY (1-800-222-1222).

KEEP OUT OF REACH OF CHILDREN

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DIRECTIONS

ADULTS AND CHILDREN 12 YEARS OF AGE AND OLDER: USE ONCE A DAY AFTER BRUSHING YOUR TEETH WITH A 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 12 YEARS OF AGE: CONSULT A DENTIST OR DOCTOR.

OTHER INFORMATION

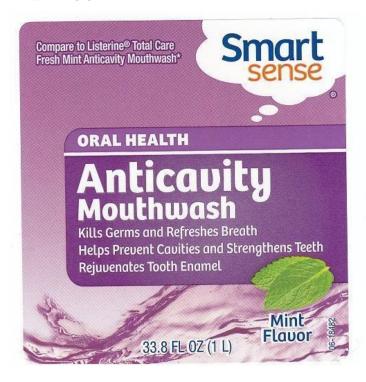
STORE AT CONTROLLED ROOM TEMPERATURE 20-25C (68-77F). COLD WEATHER MAY CLOUD THIS PRODUCT.

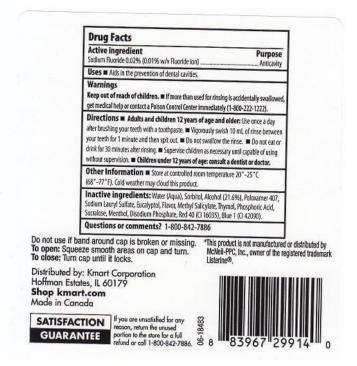
INACTIVE INGREDIENTS:

WATER (AQUA), SORBITOL, ALCOHOL (21.6%), POLOXAMER 407, SODIUM LAURYL SULFATE, EUCALYPTOL, FLAVOR, METHYL SALICYLATE, THYMOL, PHOSPHORIC ACID, SUCRALOSE, MENTHOL, DISODIUM PHOSPHATE, RED 40 (CI 16035), BLUE 1 (CI 42090).

QUESTIONS OR COMMENTS?

LABEL COPY





SMART SENSE ANTICAVITY

sodium fluoride liquid

Product Information

Product TypeHUMAN OTC DRUGItem Code (Source)NDC:49738-552

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name
Basis of Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80 VPU408O)
FLUORIDE ION
0.2 mg in 1 mL

Inactive Ingredients Ingredient Name Strength WATER (UNII: 059QF0K00R) SORBITOL (UNII: 506T60A25R) ALCOHOL (UNII: 3K9958V90M) POLOXAMER 407 (UNII: TUF2IVW3M2) SODIUM LAURYL SULFATE (UNII: 368GB5141J) EUCALYPTOL (UNII: RV6J6604TK) METHYL SALICYLATE (UNII: LAV5U5022Y) THYMOL (UNII: 3J50XA376E) PHOSPHORIC ACID (UNII: E4GA8884NN)

SUCRALOSE (UNII: 96K6UQ3ZD4)	
MENTHOL (UNII: L7T10EIP3A)	
SO DIUM PHO SPHATE, DIBASIC, ANHYDRO US (UNII: 22ADO 53M6 F)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

P	Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:49738-552-34	1000 mL in 1 BOTTLE, PLASTIC					

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph final	part355	05/09/2013				

Labeler - KMART CORPORATION (008965873)

Registrant - APOLLO HEALTH AND BEAUTY CARE (201901209)

Establishment						
Name	Address	ID/FEI	Business Operations			
APOLLO HEALTH AND BEAUTY CARE		201901209	manufacture(49738-552)			

Revised: 5/2013 KMART CORPORATION