DISCOUNT DRUG MART ANTICAVITY FLUORIDE RINSE MINT FLAVOR- sodium fluoride liquid DISCOUNT DRUG MART

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

ANTIPLAQUE

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

DIRECTIONS

ADULTS AND CHILDREN 6 YEARS OF AGE AND OLDER: USE 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

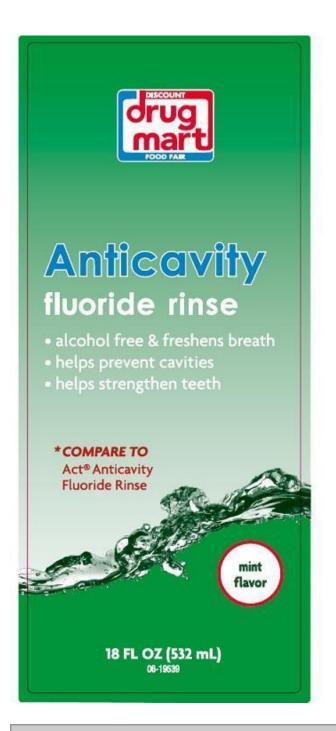
OTHER INFORMATION

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).

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Drug Facts

Active ingredient

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

Purpose Antiplaque

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.

Directions

■ Adults and children 6 years of age and older:

- use 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 (Cl 42053), Menthol, Methyl Salicylate, Poloxamer 407, Polysorbate 20, Potassium Sorbate, Propylene Glycol, Sodium Benzoate, Sodium Phosphate, Sodium Saccharin, Sorbitol, Water (Aqua), Yellow 5 (Cl 19140).

DO NOT USE IF BAND AROUND CAP IS BROKEN OR MISSING. TO OPEN: SQUEEZE SMOOTH AREAS ON CAP AND TURN. TO CLOSE: TURN CAP UNTIL IT LOCKS.

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

Distributed by: Discount Drug Mart Inc. Medina, 0H 44256 www.discount-drugmart.com Made in Canada

SATISFACTION GUARANTEED IF DISSATISFIED, RETURN UNUSED PORTION AND PACKAGE

IF DESATISFIED, RETURN LAUSED PORTION AND PACKAGE TO STORE WHERE PURICHASED, IF UNABLE TO RETURN TO STORE, SEND REASON FOR DISSATISFACTION, NAME, ADDRESS AND EMPTY PACKAGE TO: DISCOUNT DRUG MART, 211 COMMERCE DRIVE, MEDINA, OHIO 44256



08-19540

DISCOUNT DRUG MART ANTICAVITY FLUORIDE RINSE MINT FLAVOR

sodium fluoride liquid

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:53943-554

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80 VPU408O)	FLUORIDE ION	0.5 mg in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
EDETATE CALCIUM DISO DIUM (UNII: 25IH6 R4SGF)	
CETYLPYRIDINIUM CHLO RIDE (UNII: D9 O M4 S K49 P)	
SO DIUM PHO SPHATE, DIBASIC, ANHYDRO US (UNII: 22ADO53M6F)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	
MENTHOL (UNII: L7T10EIP3A)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SO DIUM PHO SPHATE (UNII: SE337SVY37)	
SACCHARIN SODIUM (UNII: SB8 ZUX40 TY)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

F	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:53943-554-18	532 mL in 1 BOTTLE, PLASTIC				

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part355	05/15/2014		

Labeler - DISCOUNT DRUG MART (047741335)

Registrant - APOLLO HEALTH AND BEAUTY CARE (201901209)

Establishment				
Name	Address	ID/FEI	Business Operations	
APOLLO HEALTH AND BEAUTY CARE		201901209	manufacture(53943-554)	

Revised: 5/2014 DISCOUNT DRUG MART