KROGER KIDS ANTICAVITY FLUORIDE MIXED BERRY- sodium fluoride liquid The Kroger Company

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

Use

• 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

- DAdults and children 6 years of age and older:
- Duse twice daily after brushing your teeth with a toothpaste
- vigorously swish 10 mL (2 teaspoonfuls) 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

Other information

- Store at controlled room temperature 20°-25°C (68°-77°F)
- Cold weather may cloud this product.

Inactive ingredients

Water (Aqua), Xylitol, Glycerin, Zinc Chloride, Benzoic Acid, Flavor (Aroma), Methylparaben.

Questions or Comments?

1-800-632-6900

Label Copy



KROGER KIDS ANTICAVITY FLUORIDE MIXED BERRY

sodium fluoride liquid

	JUMAN OTO DDUG		``	NDC-20142 502	
Product Type	HUMAN OTC DRUG	Item Code (Sour	rce)	NDC:30142-563	
Route of Administration	ORAL				
Active Ingredient/Active Mo	ety				
Ingredient Name Basis of S			Basis of Str	enoth	Carrow walk
1118			Dubib 01 5th	cingtin	Strength
SODIUM FLUORIDE (UNII: 8 ZYQ 1474		VPU408O)	FLUORIDE ION	-	-
	W7) (FLUORIDE ION - UNII:Q80	VPU408O)		1	0.2 mg in 1 m
SODIUM FLUORIDE (UNII: 8 ZYQ 1474		VPU408O)		1	-
SODIUM FLUORIDE (UNII: 8ZYQ1474	W7) (FLUORIDE ION - UNII:Q80	VPU408O)		1	0.2 mg in 1 ml
SODIUM FLUORIDE (UNII: 8ZYQ1474 Inactive Ingredients WATER (UNII: 059QF0K00R)	W7) (FLUORIDE ION - UNII:Q80	VPU408O)		1	0.2 mg in 1 m
SODIUM FLUORIDE (UNII: 8ZYQ1474 Inactive Ingredients WATER (UNII: 059QF0K00R) XYLITOL (UNII: VCQ006KQ1E)	W7) (FLUORIDE ION - UNII:Q80 Ingredient Name	VPU408O)		1	0.2 mg in 1 m
SODIUM FLUORIDE (UNII: 8ZYQ1474 Inactive Ingredients WATER (UNII: 059QF0K00R) XYLITOL (UNII: VCQ006KQ1E) GLYCERIN (UNII: PDC6A3C0OX)	W7) (FLUORIDE ION - UNII:Q80 Ingredient Name	VPU408O)		1	0.2 mg in 1 m

Packaging								
#	Item Code	Package Description		Marketing Start Date	Marketing End Date			
1) mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination duct		0 1/20 /20 17				
Marketing Information								
N	larketing Catego	ry Application Number or Monograph Citation	Ma	rketing Start Date	Marketing End Date			
0	TC monograph fina	l part355	0 1/2	0/2017				

Labeler - The Kroger Company (006999528)

Registrant - Apollo Health and Beauty Care Inc. (201901209)

Establishment

Name	Address	ID/FEI	Business Operations
Apollo Health and Beauty Care Inc.		201901209	manufacture(30142-563)

Revised: 1/2017

The Kroger Company