HOO GARGLE APPLE SPEARMINT FLAVOR- sodium fluoride liquid Nuriearth Global Co., Ltd.

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.

Hoo Gargle Apple Spearmint Flavor Active Ingredient

Sodium Flouride 0.02%

Hoo Gargle Apple Spearmint Flavor Ask Doctor

Children under 6 years of age: consult a dentist or doctor

Hoo Gargle Apple Spearmint Flavor Warning

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 right away.

Hoo Gargle Apple Spearmint Flavor Keep Out of Reach of Children

Keep out of reach of children. If more than used for rinsing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Hoo Gargle Apple Spearmint Flavor Questions

Questions/Comments:

Call +1-203-908-5154

Hoo Gargle Apple Spearmint Flavor Directions

Directions

adults and children 6 years of age and older:

use before or after brushing your teeth with a toothpaste or use whenever you want but do not use more than 3 times a day vigorously swish 10mililiters (2 teaspoonfuls) of rinse between your teeth for 1 minutes 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

Hoo Gargle Apple Spearmint Flavor Inactive Ingredient

water, L-menthol, xylitol, sodium acetate, alanine, acetic acid, propolis, chitosan, green tea extract. stevia, cyclodextrin. benzoic acid. red ginsengs extract, caramel. grapefruit seed extract, maple flavor, apple spearmint flavor

Hoo Gargle Apple Spearmint Flavor Indications

aids in the prevention of dental cavities

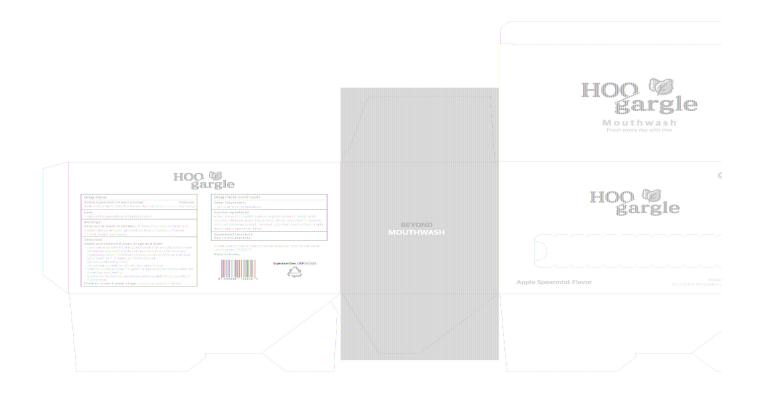
Hoo Gargle Apple Spearmint Flavor Purpose

anticavity

Hoo Gargle Apple Spearmint Flavor Package Label









HOO GARGLE APPLE	SPEARMINT FL	AVOR				
sodium fluoride liquid						
Product Information						
Product Type	HUMAN OTC DRUG	Item Code (Source)		NDC:83367-100		
Route of Administration	ORAL					
Active Ingredient/Active Moiety						
Ingredient Name			Basis of Stre	ngth	Stre	ngth
SODIUM FLUORIDE (UNII: 8ZYQ14	74W7) (FLUORIDE ION - UNI	I:Q80VPU408O)		Ξ 0.	.2 mg	in 1 mL
Inactive Ingredients						

Ingredient Name	Strength
XYLITOL (UNII: VCQ006KQ1E)	10 mg in 1 mL
ALANINE (UNII: OF5P57N2ZX)	0.5 mg in 1 mL
(2-AMINO-5,6-DICHLOROQUINAZOLIN-3(4H)-YL)ACETIC ACID (UNII: 03TUA9L576)	0.5 mg in 1 mL
MENTHOL (UNII: L7T10EIP3A)	0.6 mg in 1 mL
SODIUM ACETATE (UNII: 4550K0SC9B)	0.5 mg in 1 mL

Packaging

#	ltem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83367-100- 02	1 in 1 PACKAGE	04/01/2023	
1	NDC:83367-100- 01	15 mL in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:83367-100- 04	1 in 1 PACKAGE	04/01/2023	
2	NDC:83367-100- 03	30 mL in 1 PACKET; Type 0: Not a Combination Product		
3	NDC:83367-100- 06	1 in 1 PACKAGE	04/01/2023	
3	NDC:83367-100- 05	50 mL in 1 PACKET; Type 0: Not a Combination Product		
4	NDC:83367-100- 08	1 in 1 PACKAGE	04/01/2023	
4	NDC:83367-100- 07	100 mL in 1 PACKET; Type 0: Not a Combination Product		
M	larketing	Information		

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Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M022	04/01/2023	

Labeler - Nuriearth Global Co., Ltd. (695456265)

Registrant - Nuriearth Global Co., Ltd. (695456265)

Establishment

Name	Address	ID/FEI	Business Operations
Miko Co Ltd		695188803	manufacture(83367-100)

Revised: 4/2023

Nuriearth Global Co., Ltd.