HOO GARGLE ROOIBOS TEA 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 Rooibos Tea Flavor Active Ingredient

Sodium Flouride 0.02%

Hoo Gargle Rooibos Tea Flavor Purpose

anticavity

Hoo Gargle Rooibos Tea 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 Rooibos Tea 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 Rooibos Tea Flavor Indication

aids in the prevention of dental cavities

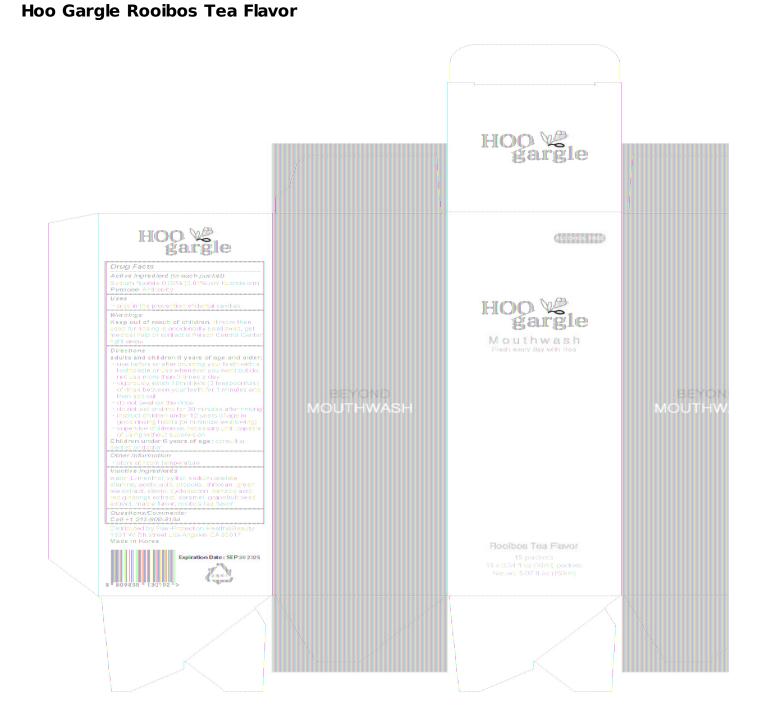
Hoo Gargle Rooibos Tea Flavor Inactive Ingredients

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, rooibos tea flavor

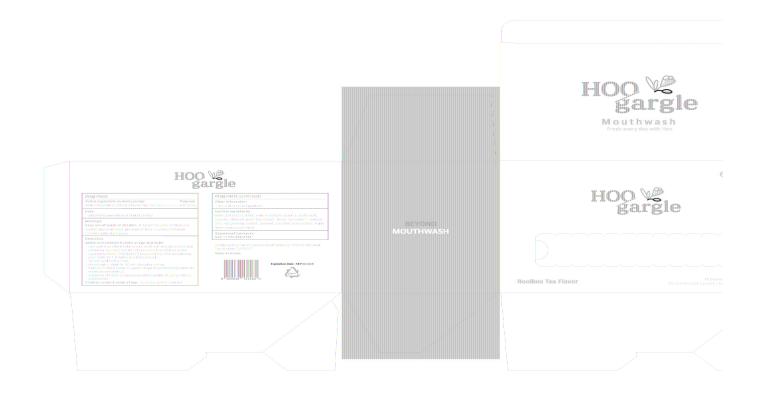
Hoo Gargle Rooibos Tea Flavor Warning

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 ROOIB	OS TEA FLAVOF	ł			
sodium fluoride liquid					
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Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)		NDC:83367-102	
Route of Administration	ORAL				
Active Ingredient/Active Moiety					
Ingree	dient Name		Basis of Stre	ngth Str	ength
SODIUM FLUORIDE (UNII: 8ZYQ14	74W7) (FLUORIDE ION - UN	II:Q80VPU408O)		E 0.2 m	g in 1 mL
Inactive Ingredients					

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

Packaging

#	ltem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83367-102- 02	1 in 1 PACKAGE	04/01/2023	
1	NDC:83367-102- 01	15 mL in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:83367-102- 04	1 in 1 PACKAGE	04/01/2023	
2	NDC:83367-102- 03	30 mL in 1 PACKET; Type 0: Not a Combination Product		
3	NDC:83367-102- 06	1 in 1 PACKAGE	04/01/2023	
3	NDC:83367-102- 05	50 mL in 1 PACKET; Type 0: Not a Combination Product		
4	NDC:83367-102- 08	1 in 1 PACKAGE	04/01/2023	
4	NDC:83367-102- 07	100 mL in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	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(83367-102)

Revised: 4/2023

Nuriearth Global Co., Ltd