GINGIMED- stannous fluoride liquid Massco Dental

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

ACTIVE INGREDIENT

STANNOUS FLUORIDE

INACTIVE INGREDIENTS

GLYCERIN, FLAVOR, XYLITOL

USE

APPROVED USES: RELIEF OF DENTINAL HYPERSENSITIVITY. CONTROL OF PERIO INFECTION.

KEEP OUT OF REACH OF CHILDREN

KEEP OUT OF REACH OF CHILDREN

DIRECTIONS FOR USE

ADULTS AND CHILDREN 6 YEARS AND OLDER: RINSE EACH DAY AFTER USUAL BRUSHING AND FLOSSING OR MORE OFTEN IF YOUR DENTIST RECOMMENDS ADDITIONAL THERAPY BASED ON THE DIAGNOSIS. PUSH DOWN ON PUMP TWICE OR POUR THE CONCENTRATED RINSE TO THE 1/8 FL. OX. MARK ON THE MIXING VIAL. ADD WATER TO THE 1 OZ. LINE. CLOSE TIGHTLY WITH SNAP-ON CAP AND SHAKE WELL. THIS PREPARES A 0.1% STANNOUS FLUORIDE RINSE. RINSE WITH ONE HALF OF THE SOLUTION FOR ONE MINUTE, EXPECTORATE (SPIT) AND REPEAT THE PROCEDURE WITH THE REMAINING HALF OF THE MIXTURE. DO NOT SWALLOW AND DO NOT RINSE MOUTH. RINSE MIXING VIAL WITH WATER AFTER EACH USE.

CHILDREN 6-12 YEARS: INSTRUCT AND SUPERVISE IN GOOD RINSING HABITS. (HELP TO MINIMIZE SWALLOWING)

CHILDREN UNDER 6: CONSULT A DENTIST.

FOR HOME IRRIGATION: PREPARE 1 OZ. OF GINGIMED RINSE AS DESCRIBED ABOVE. POUR INTO IRRIGATOR RESIVOIR AND ADD 4 OZ. OF WATER. MIX THOROUGHLY. USE IRRIGATOR AS DESCRIBED

OTHER INFORMATION

THIS PRODUCT MAY CAUSE MINIMAL SURFACE DISCOLORATION ON THE TEETH, MAY BE PREVENTED BY ADEQUATE BRUSHING.

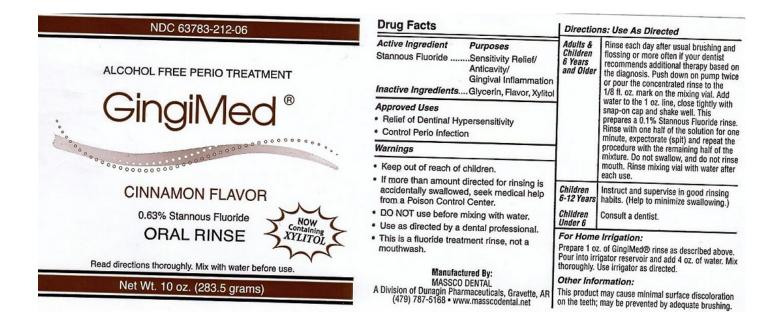
WARNINGS

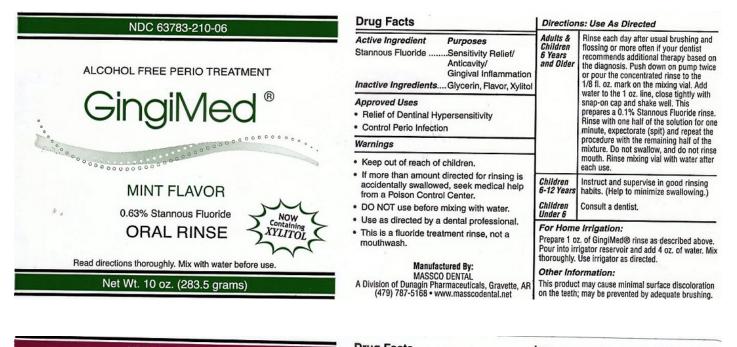
IF MORE THAN AMOUNT DIRECTED FOR RINSING IS ACCIDENTALLY SWALLOWED, SEEK MEDICAL HELP FROM A POISON CONTROL CENTER. DO NOT USE BEFORE MIXING WITH WATER. USE AS DIRECTED BY A DENTAL PROFESSIONAL. THIS IS A FLUORIDE TREATMENT RINSE, NOT A MOUTHWASH.

PACKAGE LABEL

ALCOHOL FREE PERIO TREATMENT. GINGIMED 0.63% STANNOUS FLUORIDE READ DIRECTIONS THOROUGHLY. MIX WITH WATER BEFORE USE. NOW CONTAINING XYLITOL

MANUFACTURED BY MASSCO DENTAL A DIVISION OF DUNAGIN PHARMACEUTICALS, GRAVETTE, AR (479) 787-5168 WWW.MASSCODENTAL.NET





NDC 63783-211-06	Drug Facts	Direction	ns: Use As Directed
	Active Ingredient Purposes Stannous FluorideSensitivity Relief/ Anticavity/ Gingival Inflammation Inactive IngredientsGlycerin, Flavor, Xylitol	Adults & Children 6 Years and Older	Rinse each day after usual brushing and flossing or more often if your dentist recommends additional therapy based on the diagnosis. Push down on pump twice or pour the concentrated rinse to the 1/8 fl. oz. mark on the mixing vial. Add
GingiMed [®]	Approved Uses Relief of Dentinal Hypersensitivity Control Perio Infection 		water to the 1 oz. line, close tightly with snap-on cap and shake well. This prepares a 0.1% Stannous Fluoride rinse. Rinse with one half of the solution for one minute, expectorate (spit) and repeat the
····	Warnings		procedure with the remaining half of the mixture. Do not swallow, and do not rinse
000000000000000000000000000000000000000	 Keep out of reach of children. 		mouth. Rinse mixing vial with water after each use.
CARIBBEAN ICE FLAVOR	 If more than amount directed for rinsing is accidentally swallowed, seek medical help from a Poison Control Center. 	Children 6-12 Years	Instruct and supervise in good rinsing habits. (Help to minimize swallowing.)
0.63% Stannous Fluoride	 DO NOT use before mixing with water. 	Children Under 6	Consult a dentist.
ORAL RINSE	 Use as directed by a dental professional. This is a fluoride treatment rinse, not a mouthwash. 	For Home Prepare 1 or Pour into irr	e Irrigation: z. of GingiMed® rinse as described above. igator reservoir and add 4 oz. of water. Mix
Read directions thoroughly. Mix with water before use.	Manufactured By: MASSCO DENTAL	Other Info	Use irrigator as directed.
Net Wt. 10 oz. (283.5 grams)	A Division of Dunagin Pharmaceuticals, Gravette, AR	This product	t may cause minimal surface discoloration may be prevented by adequate brushing.

res

HUMAN PRESCRIPTION DRUG	Item Co	ode (Source)	NDC:63783-210
ORAL			
мојету			
dient Name		Basis of Strength	Strength
44B32Q) (FLUORIDE ION -		FLUORIDE ION	0.19 g in 100 g
	ORAL Moiety dient Name	ORAL Moiety dient Name	ORAL Moiety dient Name Basis of Strength

Inactive Ingr	edients	5			
		Ingredient Name		9	Strength
GLYCERIN (UNII: I	PDC6A3C0	OX)			
XYLITOL (UNII: VO	Q006KQ1	E)			
Product Cha	racteri	stics			
Color			Score		
Shape			Size		
Flavor		SPEARMINT (MINT)	Imprint	Code	
Contains					
Packaging					
# Item Code		Package Description	Mai	keting Start Date	Marketing End Date
1 NDC:63783- 210-06		BOTTLE, WITH APPLICATOR; Type 0: Not a ion Product	01/0	1/1989	
Marketing	Infor	mation			
Marketing		oplication Number or Monograph	Marke	ting Start	Marketing End
Category		Citation		Date	Date
unapproved drug			01/01/19	39	

Product Information					
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:63783-211		
Route of Administration	ORAL				
Active Ingredient/Active Moiety					
Active ingredient/Active	Molecy				

Ingredient Name	Basis of Strength	Strength
STANNOUS FLUORIDE (UNII: 3FTR44B32Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.19 g in 100 g

Inactive Ingredients		
Ingredient Name	Strength	
GLYCERIN (UNII: PDC6A3C0OX)		
XYLITOL (UNII: VCQ006KQ1E)		

Product Characteris	ISTICS	50	ore	
Shape		Si		
	RAPE (CARIBBEAN ICE)		print Code	
Contains				
Packaging				
	Deskens Description	М	arketing Start	Marketing End
# Item Code	Package Description		Date	Date
	1 BOTTLE, WTH APPLICATOR; Type 0 tion Product): Not a 01,	/01/1989	
Marketing Infor	rmation			
Marketing A Category	Application Number or Monogr Citation	aph Marl	keting Start Date	Marketing End Date
unapproved drug	Citation	01/01/1	01/01/1989	
other		01/01/1	1909	
GINGIMED				
stannous fluoride liquid	1			
Product Informatio	on			
Product Type	HUMAN PRESCRIPTION DRUG	G Item Co	ode (Source)	NDC:63783-212
Route of Administratio	on ORAL			
	ation Mariator			
Active Ingredient/A			Basis of	
	Ingredient Name		Strength	Strength
STANNOUS FLUORIDE (UN UNII:Q80VPU4080)	NII: 3FTR44B32Q) (FLUORIDE ION -		FLUORIDE ION	0.19 g in 100 g
	JNII:Q80VP04080)			

Ingredient Name		Strength			
GLYCERIN (UNII: PDC6A3	3C00X)				
XYLITOL (UNII: VCQ006KQ1E)					
Product Characte	ristics				
Color		Score			
Shape		Size			

CINNAMON (CINNAMON)

Flavor

Imprint Code

Co	ontains				
Pa	ackaging				
#	ltem Code	Package Description		Marketing Start Date	Marketing End Date
	NDC:63783- 212-06 120 g in 1 BOTTLE, WTH APPLICATOR; Type 0: Not a Combination Product 01/01/1989				
Μ	larketing	Information			
	Marketing Category	Application Number or Monograph Citation	N	larketing Start Date	Marketing End Date
	approved drug her		01/	01/1989	

Labeler - Massco Dental (008081858)

Registrant - Massco Dental (008081858)

Establishment				
Name	Address	ID/FEI	Business Operations	
Massco Dental		008081858	manufacture(63783-210, 63783-211, 63783-212)	

Revised: 12/2023

Massco Dental