

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. OZ. 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



Drug Facts

Active Ingredient **Purposes**
 Stannous FluorideSensitivity Relief/
 Anticavity/
 Gingival Inflammation

Inactive Ingredients....Glycerin, Flavor, Xylitol

Approved Uses

- Relief of Dentinal Hypersensitivity
- Control Perio Infection

Warnings

- Keep out of reach of children.
- 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.

Manufactured By:
 MASSCO DENTAL

A Division of Dunagin Pharmaceuticals, Gravette, AR
 (479) 787-5168 • www.masscodental.net

Directions: Use As Directed

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 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 reservoir and add 4 oz. of water. Mix thoroughly. Use irrigator as directed.

Other Information:

This product may cause minimal surface discoloration on the teeth; may be prevented by adequate brushing.

NDC 63783-210-06

ALCOHOL FREE PERIO TREATMENT

GingiMed[®]



MINT FLAVOR

0.63% Stannous Fluoride

ORAL RINSE

**NOW
Containing
XYLITOL**

Read directions thoroughly. Mix with water before use.

Net Wt. 10 oz. (283.5 grams)

Drug Facts

<p>Active Ingredient Purposes</p> <p>Stannous FluorideSensitivity Relief/ Anticavity/ Gingival Inflammation</p> <p>Inactive Ingredients....Glycerin, Flavor, Xylitol</p> <p>Approved Uses</p> <ul style="list-style-type: none"> • Relief of Dentinal Hypersensitivity • Control Perio Infection <p>Warnings</p> <ul style="list-style-type: none"> • Keep out of reach of children. • 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. <p style="text-align: center; font-weight: bold;">Manufactured By: MASSCO DENTAL</p> <p style="font-size: x-small;">A Division of Dunagin Pharmaceuticals, Gravette, AR (479) 787-5168 • www.masscodental.net</p>	<p>Directions: Use As Directed</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 15%; font-weight: bold; font-size: small;">Adults & Children 6 Years and Older</td> <td>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 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.</td> </tr> <tr> <td style="font-weight: bold; font-size: small;">Children 6-12 Years</td> <td>Instruct and supervise in good rinsing habits. (Help to minimize swallowing.)</td> </tr> <tr> <td style="font-weight: bold; font-size: small;">Children Under 6</td> <td>Consult a dentist.</td> </tr> </table> <p>For Home Irrigation: Prepare 1 oz. of GingiMed® rinse as described above. Pour into irrigator reservoir and add 4 oz. of water. Mix thoroughly. Use irrigator as directed.</p> <p>Other Information: This product may cause minimal surface discoloration on the teeth; may be prevented by adequate brushing.</p>	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 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.
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NDC 63783-211-06

ALCOHOL FREE PERIO TREATMENT

GingiMed[®]



CARIBBEAN ICE FLAVOR

0.63% Stannous Fluoride

ORAL RINSE

**NOW
Containing
XYLITOL**

Read directions thoroughly. Mix with water before use.

Net Wt. 10 oz. (283.5 grams)

Drug Facts

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GINGIMED		
stannous fluoride liquid		
Product Information		
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source) NDC:63783-210
Route of Administration	ORAL	
Active Ingredient/Active Moiety		
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 Characteristics

Color		Score	
Shape		Size	
Flavor	SPEARMINT (MINT)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63783-210-06	120 g in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product	01/01/1989	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		01/01/1989	

GINGIMED

stannous fluoride liquid

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:63783-211
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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 Characteristics

Color		Score	
Shape		Size	
Flavor	GRAPE (CARIBBEAN ICE)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63783-211-06	120 g in 1 BOTTLE, WTH APPLICATOR; Type 0: Not a Combination Product	01/01/1989	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		01/01/1989	

GINGIMED

stannous fluoride liquid

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:63783-212
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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 Characteristics

Color		Score	
Shape		Size	
Flavor	CINNAMON (CINNAMON)	Imprint Code	

Contains**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63783-212-06	120 g in 1 BOTTLE, WTH APPLICATOR; Type 0: Not a Combination Product	01/01/1989	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		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