KIDS CHOICE- stannous fluoride gel, dentifrice Massco Dental A Division of Dunagin Pharmaceuticals

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

Active Ingredient: Stannous Fluoride

INACTIVE INGREDIENTS

Glycerine, Hydroxy Ethyl Celluulose, Xylitol

USE

Aids in the prevention of dental decay.

KEEP OUT OF REACH OF CHILDREN

KEEP OUT OF REACH OF CHILDREN

DIRECTIONS FOR USE

Adults and Children 12 years and Older: Use after regular brushing and flossing. Place gel across length of toothbrush. Brush Thoroughly. Keep on teeth for 1 - 1 1/2 minutes and then expectorate (spit out). Do not swallow. Use once a day for cavity prevention. Supervise children until capable of using without supervision.

Children 6-11 Years: See directions above. Adult supervision required.

Children Under 6: Consult a Dentist or Physician.

OTHER INFORMATION

This is a fluoride prevention treatment gel, not a toothpaste. Read directions carefully before use. This product may produce surface discoloration of the teeth. Adequate toothbrushing may prevent discoloration. Discoloration is not harmful or permanent and may be removed by a dental professional. Do not freeze or expose to extreme heat.

QUESTIONS? COMMENTS?

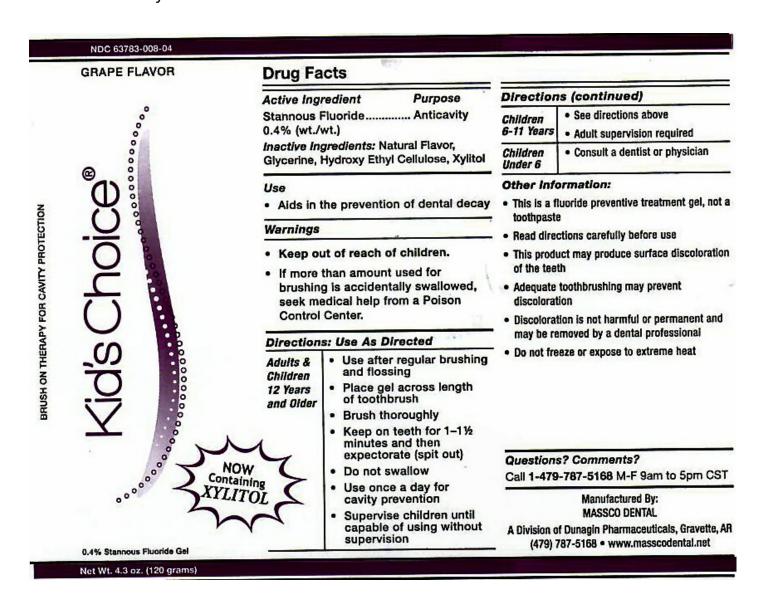
Questions?? Comments??

WARNINGS

If more than amount used for brushing is accidentally swallowed, seek medical help from a poison control center.

PACKAGE LABEL

Brush on Therapy for Cavity Prevention - Doctor's Choice 0.4% Stannous Fluoride Gel Manufactured by Massco Dental



BUBBLE GUM FLAVOR 0000000000 Use BRUSH ON THERAPY FOR CAVITY PROTECTION NOW Containing XYLITOL 0.4% Stannous Fluoride Gel

Drug Facts

Active Ingredient Purpose Stannous Fluoride..... Anticavity 0.4% (wt./wt.)

Inactive Ingredients: Natural Flavor, Glycerine, Hydroxy Ethyl Cellulose, Xylitol

Aids in the prevention of dental decay

Warnings

- Keep out of reach of children.
- If more than amount used for brushing is accidentally swallowed, seek medical help from a Poison Control Center.

Directions: Use As Directed

Adults & Children 12 Years and Older

- Use after regular brushing and flossing
- Place gel across length of toothbrush
- Brush thoroughly
- Keep on teeth for 1-11/2 minutes and then expectorate (spit out)
- Do not swallow
- Use once a day for cavity prevention
- Supervise children until capable of using without supervision

Directions (continued)

· See directions above Children 6-11 Years · Adult supervision required Children · Consult a dentist or physician Under 6

Other Information:

- . This is a fluoride preventive treatment gel, not a toothpaste
- · Read directions carefully before use
- This product may produce surface discoloration of the teeth
- Adequate toothbrushing may prevent discoloration
- Discoloration is not harmful or permanent and may be removed by a dental professional
- · Do not freeze or expose to extreme heat

Questions? Comments?

Call 1-479-787-5168 M-F 9am to 5pm CST

Manufactured By: MASSCO DENTAL

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

Net Wt. 4.3 oz. (120 grams)

LIMEADE FLAVOR 000000000 Use BRUSH ON THERAPY FOR CAVITY PROTECTION NOW Containing

Drug Facts

Active Ingredient **Purpose** Stannous Fluoride..... Anticavity 0.4% (wt./wt.)

Inactive Ingredients: Natural Flavor, Glycerine, Hydroxy Ethyl Cellulose, Xylitol

Aids in the prevention of dental decay

Warnings

- Keep out of reach of children.
- If more than amount used for brushing is accidentally swallowed, seek medical help from a Poison Control Center.

Directions: Use As Directed

Adults & Children 12 Years and Older

- · Use after regular brushing and flossing
- Place gel across length of toothbrush
- Brush thoroughly
- Keep on teeth for 1-11/2 minutes and then expectorate (spit out)
- Do not swallow
- Use once a day for cavity prevention
- Supervise children until capable of using without supervision

Directions (continued)

Children 6-11 Years See directions above

· Adult supervision required

Children Under 6

· Consult a dentist or physician

Other Information:

- This is a fluoride preventive treatment gel, not a toothpaste
- · Read directions carefully before use
- This product may produce surface discoloration of the teeth
- · Adequate toothbrushing may prevent discoloration
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Manufactured By: MASSCO DENTAL

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

0.4% Stannous Fluoride Gel Net Wt. 4.3 oz. (120 grams

Drug Facts

Active Ingredient Purpose
Stannous Fluoride...... Anticavity
0.4% (wt./wt.)

Inactive Ingredients: Natural Flavor, Glycerine, Hydroxy Ethyl Cellulose, Xylitol

· Aids in the prevention of dental decay

Warnings

- · Keep out of reach of children.
- If more than amount used for brushing is accidentally swallowed, seek medical help from a Poison Control Center.

Directions: Use As Directed

Adults & Children 12 Years and Older

- Use after regular brushing and flossing
- Place gel across length of toothbrush
- Brush thoroughly
- Keep on teeth for 1–1½ minutes and then expectorate (spit out)
- Do not swallow
- Use once a day for cavity prevention
- Supervise children until capable of using without supervision

Directions (continued)

Children 6-11 Years

- See directions above
- Adult supervision required

Children Under 6 · Consult a dentist or physician

Other Information:

- This is a fluoride preventive treatment gel, not a toothpaste
- · Read directions carefully before use
- This product may produce surface discoloration of the teeth
- Adequate toothbrushing may prevent discoloration
- Discoloration is not harmful or permanent and may be removed by a dental professional
- . Do not freeze or expose to extreme heat

Questions? Comments?

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Manufactured By: MASSCO DENTAL

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

0.4% Stannous Fluoride Gel

Net Wt. 4.3 oz. (120 grams)

BRUSH ON THERAPY FOR CAVITY PROTECTION

Drug Facts

Active Ingredient Purpose
Stannous Fluoride...... Anticavity
0.4% (wt./wt.)

Inactive Ingredients: Natural Flavor, Glycerine, Hydroxy Ethyl Cellulose, Xylitol

Use

Aids in the prevention of dental decay

Warnings

- Keep out of reach of children.
- If more than amount used for brushing is accidentally swallowed, seek medical help from a Poison Control Center.

Directions: Use As Directed

Adults & Children 12 Years and Older

NOW

Containing

- Use after regular brushing and flossing
- Place gel across length of toothbrush
- Brush thoroughly
- Keep on teeth for 1-1½ minutes and then expectorate (spit out)
- . Do not swallow
- Use once a day for cavity prevention
- Supervise children until capable of using without supervision

Directions (continued)

Children 6-11 Years

- See directions above
- Adult supervision required

Children Under 6 Consult a dentist or physician

Other Information:

- This is a fluoride preventive treatment gel, not a toothpaste
- Read directions carefully before use
- This product may produce surface discoloration of the teeth
- Adequate toothbrushing may prevent discoloration
- Discoloration is not harmful or permanent and may be removed by a dental professional
- Do not freeze or expose to extreme heat.

Questions? Comments?

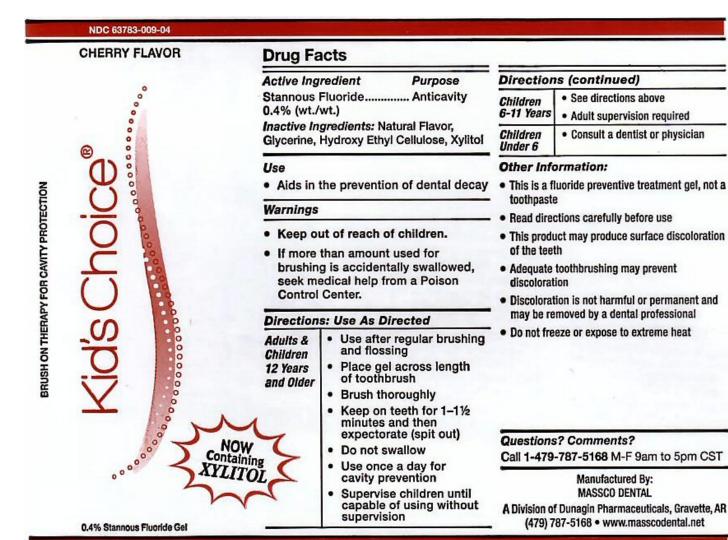
Call 1-479-787-5168 M-F 9am to 5pm CST

Manufactured By: MASSCO DENTAL

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

0.4% Stannous Fluoride Gel

Net Wt. 4.3 oz. (120 grams)



stannous fluoride gel, dentifrice

Net Wt. 4.3 oz. (120 grams)

Product Information

Route of Administration

Product Type HUMAN PRESCRIPTION DRUG Item Code (Source) NDC:63783-005

Active Ingredient/Active Moiety

ORAL

Ingredient Name	Basis of Strength	Strength
STANNOUS FLUORIDE (UNII: 3FTR44B32Q) (FLUORIDE ION - UNII: Q80VPU408O)	FLUORIDE ION	0.12 g in 120 g

Inactive Ingredients	
Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROXYETHYL CELLULOSE (2000 CPS AT 1%) (UNII: S38 6RZ N16)	

Product Characteristics		
Color		Score
Shape		Size
Flavor	BUBBLE GUM (BUBBLE GUM)	Imprint Code
Contains		

l	P	Packaging			
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:63783- 005-04	120 g in 1 BOTTLE, DISPENSING; 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	

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:63783-006
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
STANNOUS FLUORIDE (UNII: 3FTR44B32Q) (FLUORIDE ION - UNII: Q80VPU408O)	FLUORIDE ION	0.12 g in 120 g	

Inactive Ingredients	
Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROXYETHYL CELLULOSE (2000 CPS AT 1%) (UNII: S38J6RZ N16)	
XYLITOL (UNII: VCQ006KQ1E)	

Product Chara	cteristics	
Color	Score	

Shape		Size
Flavor	CREME DE MENTHE (HINT OF MINT)	Imprint Code
Contains		

	Packaging			
4	tem Code	Package Description	Marketing Start Date	Marketing End Date
7	NDC:63783- 006-04	120 g in 1 BOTTLE, DISPENSING; 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	

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:63783-007
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
STANNOUS FLUORIDE (UNII: 3FTR44B32Q) (FLUORIDE ION - UNII: Q80VPU408O)	FLUORIDE ION	0.12 g in 120 g

Inactive Ingredients	
Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROXYETHYL CELLULOSE (2000 CPS AT 1%) (UNII: S38J6RZN16)	
XYLITOL (UNII: VCQ006KQ1E)	

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	LIME (LIMEAIDE)	Imprint Code	
Contains			

I	P	ackaging			
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:63783- 007-04	120 g in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	01/01/1989	

Marketing Information				
Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
	01/01/1989			
1	Application Number or Monograph	Application Number or Monograph Marketing Start Citation Date		

l	Product Information			
	Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:63783-008
	Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
STANNOUS FLUORIDE (UNII: 3FTR44B32Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.12 g in 120 g

Inactive Ingredients	
Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROXYETHYL CELLULOSE (2000 CPS AT 1%) (UNII: S38J6RZ N16)	
XYLITOL (UNII: VCQ006KQ1E)	

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	GRAPE (GRAPE)	Imprint Code	
Contains			

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
	g in 1 BOTTLE, DISPENSING; Type 0: Not a mbination Product	01/01/1989	

Marketing Information			
Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
	01/01/1989		
	Application Number or Monograph	Application Number or Monograph Marketing Start Citation Date	

Product	Inform	ation

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:63783-009
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
STANNOUS FLUORIDE (UNII: 3FTR44B32Q) (FLUORIDE ION - UNII: Q80VPU408O)	FLUORIDE ION	0.12 g in 120 g

Inactive Ingredients		
Ingredient Name	Strength	
GLYCERIN (UNII: PDC6A3C0OX)		
HYDROXYETHYL CELLULOSE (2000 CPS AT 1%) (UNII: S38J6RZ N16)		
XYLITOL (UNII: VCQ006KQ1E)		

Product Characteristics		
Color		Score
Shape		Size
Flavor	CHERRY (CHERRY)	Imprint Code
Contains		

ı	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:63783- 009-04	120 g in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	01/01/1989	

Marketing In	formation		
Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date

stannous fluoride gel, dentifrice

Product	Inform	ation
Product	Intorm	ation

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
STANNOUS FLUORIDE (UNII: 3FTR44B32Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.12 g in 120 g

Inactive Ingredients	
Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROXYETHYL CELLULOSE (2000 CPS AT 1%) (UNII: S38J6RZ N16)	
XYLITOL (UNII: VCQ006KQ1E)	

Product Characteristics		
Color		Score
Shape		Size
Flavor	COTTON CANDY (COTTON CANDY)	Imprint Code
Contains		

Item Code Package Description Marketing Start Date Marketing End Date

1 NDC:63783- 120 g in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product 01/01/1989

Marketing Information

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

Registrant - Massco Dental A Division of Dunagin Pharmaceuticals (008081858)

Establishment					
Name	Address	ID/FEI	Business Operations		
Massco Dental A Division of Dunagin Pharmaceuticals		008081858	manufacture(63783-005, 63783-006, 63783-007, 63783-008, 63783-009, 63783-015)		

Revised: 12/2023

Massco Dental A Division of Dunagin Pharmaceuticals