

DOCTORS 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 Cellulose, Natural Flavor, 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??

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

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

NDC 63783-012-04

CINNAMON FLAVOR

BRUSH ON THERAPY FOR CAVITY PROTECTION

Doctor's Choice™



**NOW
Containing
XYLITOL**

0.4% Stannous Fluoride Gel

Net Wt. 4.3 oz. (120 grams)

Drug Facts

Active Ingredient	Purpose
Stannous Fluoride..... 0.4% (wt./wt.)	Anticavity
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	Directions
	<ul style="list-style-type: none">• 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	Directions
	<ul style="list-style-type: none">• See directions above• Adult supervision required
Children Under 6	Directions

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

MINT FLAVOR

BRUSH ON THERAPY FOR CAVITY PROTECTION

Doctor's Choice™



**NOW
Containing
XYLITOL**

Drug Facts

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

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 |
|---|
| <ul style="list-style-type: none"> • 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 | <ul style="list-style-type: none"> • See directions above • Adult supervision required |
| Children Under 6 | <ul style="list-style-type: none"> • 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)

NDC 63783-016-04

DOCTOR'S CHOICE



NATURAL

*Totally Water Free
Contains a Stable 0.4%
Stannous Fluoride*

**This medicine available exclusively
through your dental office.**

Aids in the prevention of dental decay

Net Wt. 120 grams (4.3 ozs.)

This is a fluoride treatment gel and not toothpaste.
Read directions carefully before using.

DIRECTIONS: Adults and children 6 years of age and older: Use once a day after brushing your teeth with toothpaste. Apply the gel to your teeth and brush thoroughly. Allow the gel to remain on your teeth for 1 minute and then spit out. Do not swallow the gel. Do not eat or drink for 30 minutes after brushing. Instruct children under 12 years of age in the use of this product (to minimize swallowing). Supervise children as necessary until capable of using without supervision. Children under 6 years of age consult a dentist or doctor.

WARNINGS: Keep this and all drugs out of the reach of children. If you accidentally swallow more than used for brushing, seek professional assistance or contact a poison control center immediately. This product may produce surface staining of the teeth. Adequate tooth brushing may prevent these stains which are not harmful or permanent and may be removed by your dentist.

 Manufactured by **MASSCO Dental** 
A division of DUNAGIN Pharmaceuticals - Gravette, AR 72736
www.masscodental.net

BRUSH — Times Daily RECALL — / — / —

CARIBBEAN ICE FLAVOR

BRUSH ON THERAPY FOR CAVITY PROTECTION

Doctors Choice™



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

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	<ul style="list-style-type: none"> • 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
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Directions (continued)

Children 6-11 Years	<ul style="list-style-type: none"> • See directions above • Adult supervision required
Children Under 6	<ul style="list-style-type: none"> • 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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DOCTORS CHOICE

stannous fluoride gel, dentifrice

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:63783-011
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	SPEARMINT (MINT FLAVOR)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63783-011-04	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	

DOCTORS CHOICE

stannous fluoride gel, dentifrice

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:63783-012
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	CINNAMON (CINNAMON FLAVOR)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63783-012-04	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	

DOCTORS CHOICE

stannous fluoride gel, dentifrice

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:63783-013
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	GRAPE (CARIBBEAN ICE FLAVOR)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63783-013-04	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	

DOCTORS CHOICE

stannous fluoride gel, dentifrice

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:63783-016
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)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63783-016-04	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	

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

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(63783-011, 63783-012, 63783-013, 63783-016)