DOCTORS CHOICE- stanous 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, Natural Flavor, Xylitol

USE

Aids in the prevention of dental decay.

KEEP OUT OF REACH OF CHILDREN

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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?

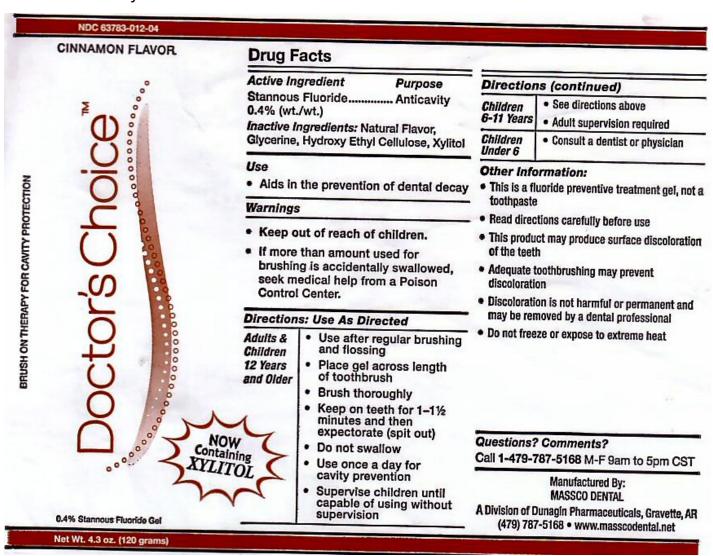
Questions?? Comments??

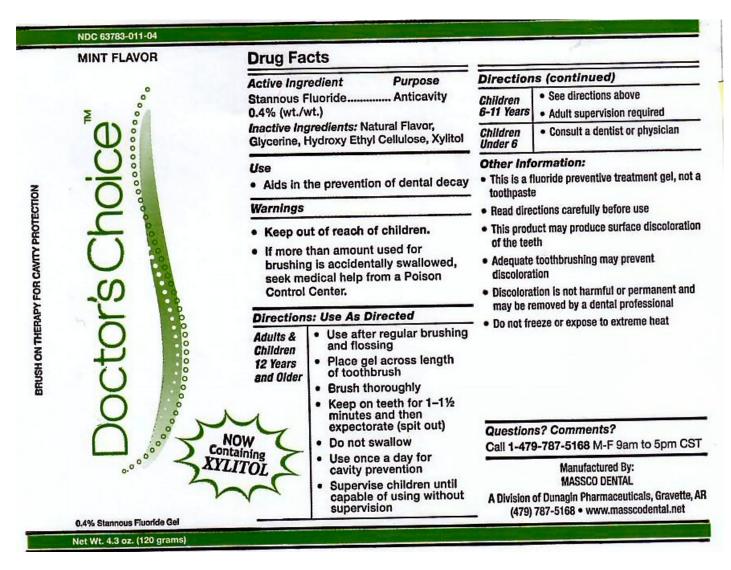
WARNINGS

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





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DOCTORS CHOICE

stanous 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 STANNOUS FLUORIDE (UNII: 3FTR44B32Q) (FLUORIDE ION - UNII: Q80VPU408O) FLUORIDE ION 0.12 g in 120 g

Inactive Ingredients	
Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	

XYLITOL (UNII: VCQ006KQ1E)

Product	Chara	cter	istics
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Color		Score			
Shape		Size			
Flavor	SPEARMINT (MINT FLAVOR)	Imprint Code			
Contains					

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

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Active Ingredient/Active Moiety

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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		

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	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			
otilei					

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)		

Revised: 12/2023 Massco Dental A Division of Dunagin Pharmaceuticals