PERIOMED- stannous fluoride rinse Solventum US OpCo LLC

Drug Facts

Active ingredient

Stannous fluoride 0.63% w/w (0.19% w/v flouride ion)

Purpose

anticavity, antigingivitis, antihypersensitivity, mouthrinse

Uses

- aids in the prevention of childhood dental decay
- helps prevent gingivitis
- helps control plaque bacteria
- builds increasing protection against painful tooth sensitivity

Warnings

- When using this product do not use for sensitivity longer than four weeks unless recommended by a dentist.
- Stop use and ask a doctor if sensitivity persists or worsens.
- Sensitive teeth may indicate a serious problem that may need prompt care.
- **Keep out of reach of children.** If more than used for rinsing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Directions

adults and children 6 years of age and older:

- do not use before mixing with water
- use immediately after preparing the rinse
- use as directed by a dental professional
- use once a day after brushing your teeth with a toothpaste or as directed by your dentist
- remove cap and seal and replace with pump
- rotate spout counter clockwise to extend
- depress pump until medicine comes to the tip of the pump
- put 1/8 oz. (approx. 2 pump strokes) of concentrated PerioMed Rinse into the provided mixing vial
- add water to 1 oz. line on mixing vial
- tightly snap on the cap and shake well

- vigorously swish rinse between your teeth for 1 minute and then spit out
- do not swallow the rinse
- do not eat or drink for 30 minutes after rinsing
- instruct children in good rinsing habits (to minimize swallowing)
- supervise children as necessary until capable of using without supervision

children under 6 years of age:

consult a dentist or doctor

Other information

- For professional use only
- products containing stannous fluoride may produce surface staining of the teeth
- adequate toothbrushing may prevent these stains which are not harmful and may be removed by your dentist
- see your dentist regularly
- this product is not intended for home or unsupervised consumer use
- for your protection, do not use if seal under the cap is broken or missing

Inactive ingredients

flavor, glycerin, methyl paraben, propyl paraben, sodium saccharin

Questions or comments?

1-800-634-2249

Principal Display Panel - Box Label (Mint - 283.5 g)

NDC 48878-3315-0

Mint

3M ESPE

PerioMed™

0.63% Stannous

Fluoride Concentrate

Antimicrobial

Oral Rinse

Non-Alcohol

Formula

IMPORTANT: Read

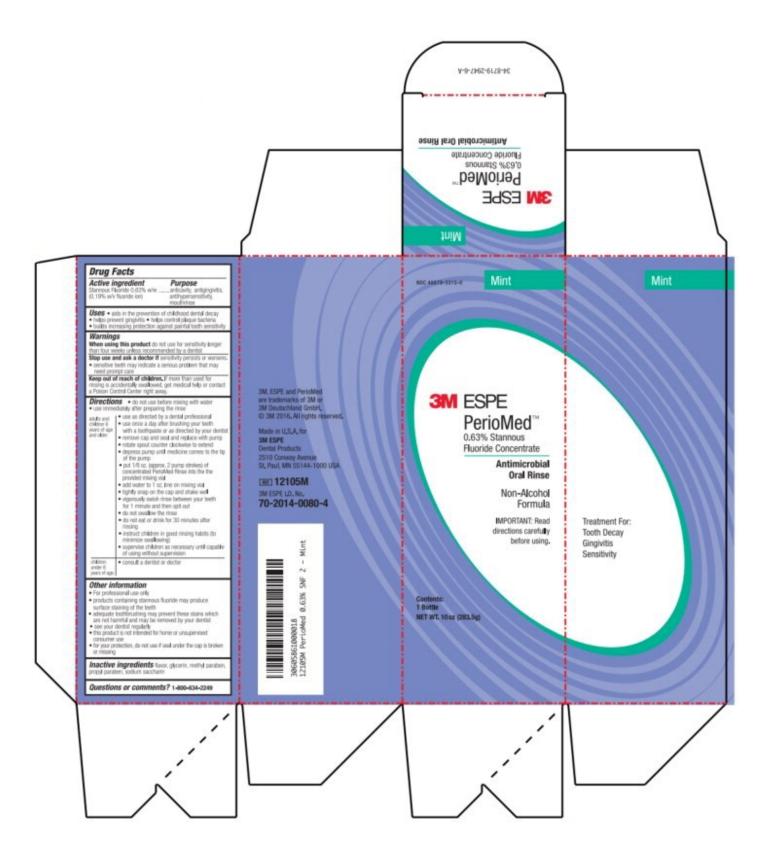
directions carefully

before using.

Contents:

1 Bottle

NET WT. 10 oz (283.5g)



NDC 48878-3315-2

Mint

3M ESPE

PerioMed™

0.63% Stannous

Fluoride Concentrate

Antimicrobial

Oral Rinse

Non-Alcohol

Formula

IMPORTANT: Read

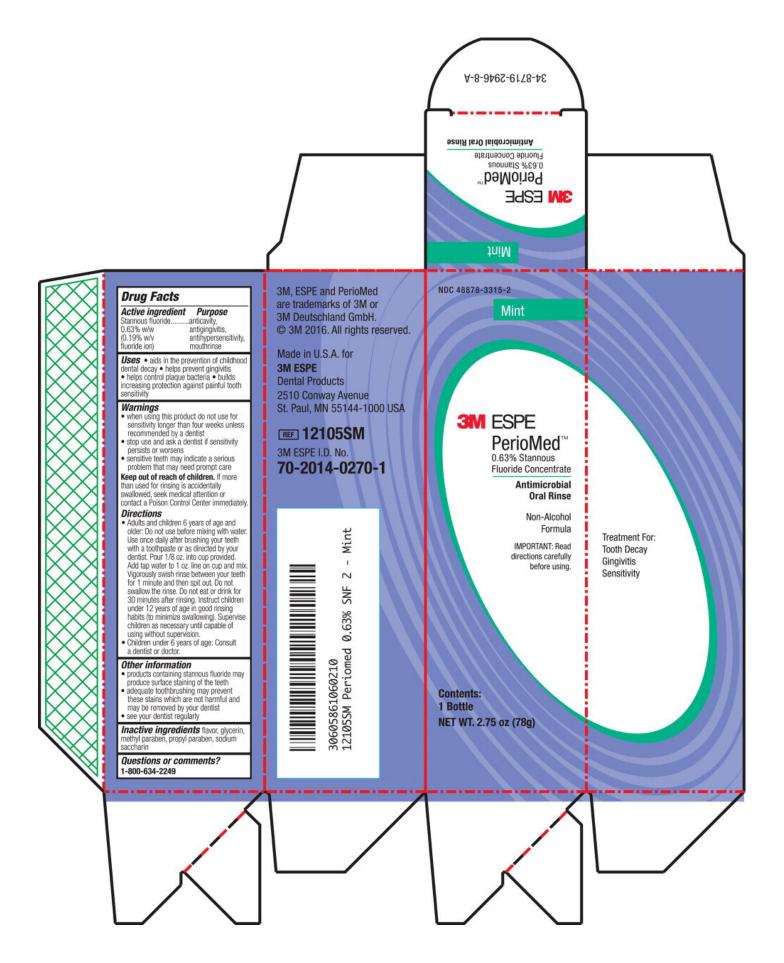
directions carefully

before using.

Contents:

1 Bottle

NET WT. 2.75 oz (78g)



Principal Display Panel - Box Label (Tropical Fruit - 283.5 g)

Tropical Fruit

3M ESPE

PerioMed™

0.63% Stannous

Fluoride Concentrate

Antimicrobial

Oral Rinse

Non-Alcohol

Formula

IMPORTANT: Read

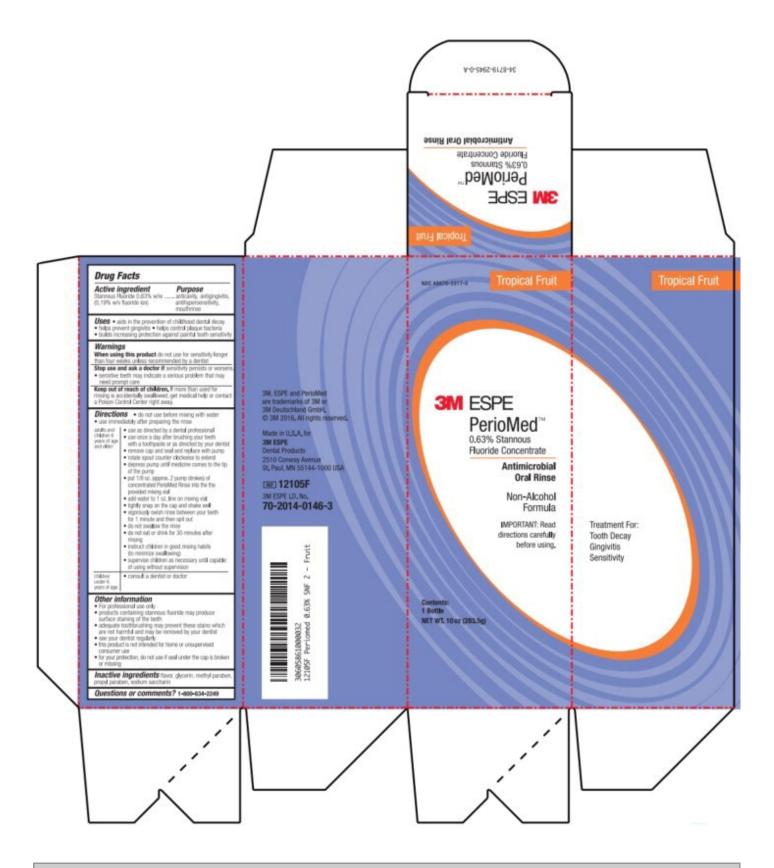
directions carefully

before using.

Contents:

1 Bottle

NET WT. 10 oz (283.5g)



PERIOMED

stannous fluoride rinse

Product Information			
MAN OTC DRUG	Item Code (Source)	NDC:48878-3315	
AL			
		110111 20010 (2001100)	

Active Ingredient/Active Moiety

Ina	red	ient	Na	me
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Basis of Strength Strength

Stannous Fluoride (UNII: 3FTR44B32Q) (Fluoride Ion - UNII:Q80VPU408O)

Fluoride Ion

1.53 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
Glycerin (UNII: PDC6A3C0OX)	
Methylparaben (UNII: A2I8C7HI9T)	
Propylparaben (UNII: Z8IX2SC1OH)	
Saccharin (UNII: FST467XS7D)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:48878- 3315-0	1 in 1 BOX	07/01/1967	
1		283.5 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:48878- 3315-2	1 in 1 BOX	02/01/2016	
2		85 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

- 101 Mounty 111011			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M021	07/01/1967	

PERIOMED

stannous fluoride rinse

Product	Inform	ation
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Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:48878-3317

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name

Basis of Strength

Stannous Fluoride (UNII: 3FTR44B32Q) (Fluoride Ion - UNII:Q80VPU408O)

Fluoride Ion

Strength 1.53 mg in 1 g

Inactive	Ingredients

Ingredient Name	Strength	
Glycerin (UNII: PDC6A3C0OX)		
Methylparaben (UNII: A2I8C7HI9T)		
Propylparaben (UNII: Z8IX2SC1OH)		
Saccharin (UNII: FST467XS7D)		

Product Characteristics

Color		Score	
Shape		Size	
Flavor	FRUIT (FRUIT)	Imprint Code	
Contains			

Packaging

i deltaging				
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:48878-3317-0	1 in 1 BOX	07/01/1967	
	1	283.5 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M021	07/01/1967	

Labeler - Solventum US OpCo LLC (801390852)

Revised: 4/2024 Solventum US OpCo LLC