JUST FOR KIDS- stannous fluoride gel Solventum US OpCo LLC

Just For Kids

Drug Facts

Active ingredient

Stannous fluoride 0.4% w/w (0.12% w/f fluoride ion)

Purpose

Anticavity

Use

Aids in the prevention of dental decay

Warnings

- This is a fluoride preventive treatment gel, not a toothpaste. Read directions carefully before using.
- **Keep out of reach of children.** If more than used for brushing is accidentally swallowed, gel medical help or contact a Poison Control Center right away.
- This product may produce surface staining of the teeth. Adequate toothbrushing may prevent these stains which are not harmful or permanent and may be removed by your dentist.

Directions

- Adults and children 6 years of age and older: Use a pea-sized (.25g) dose once a day
 after brushing your teeth with a 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.

Other information

- Do not freeze or expose to extreme heat.
- Do not use if tamper evident seal on top of box is broken or removed.

Inactive ingredients

ascorbic acid, carbomer, citric acid, flavor, glycerin, triethanolamine

Questions or comments?

call toll free M-F 9am to 5pm EST/EDT at 1-800-634-2249

Principle Display Panel - Grape

Grapey Grape

NDC 48878-4020-3

3M ESPE

Just For Kids™

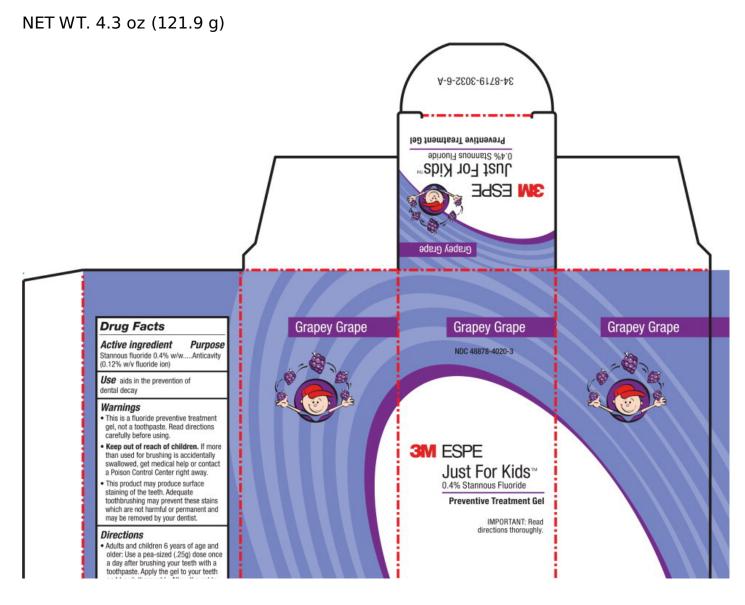
0.4% Stannous Fluoride

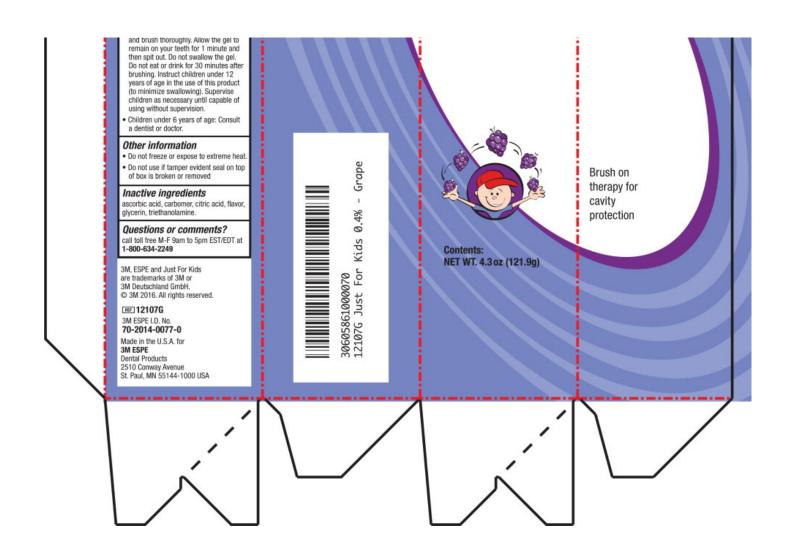
Preventive Treatment Gel

IMPORTANT: Read

directions thoroughly.

Contents:





Principle Display Panel - Bubble Gum

Bubble Gum

NDC 48878-4070-3

3M ESPE

Just For Kids™

0.4% Stannous Fluoride

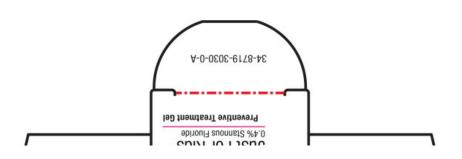
Preventive Treatment Gel

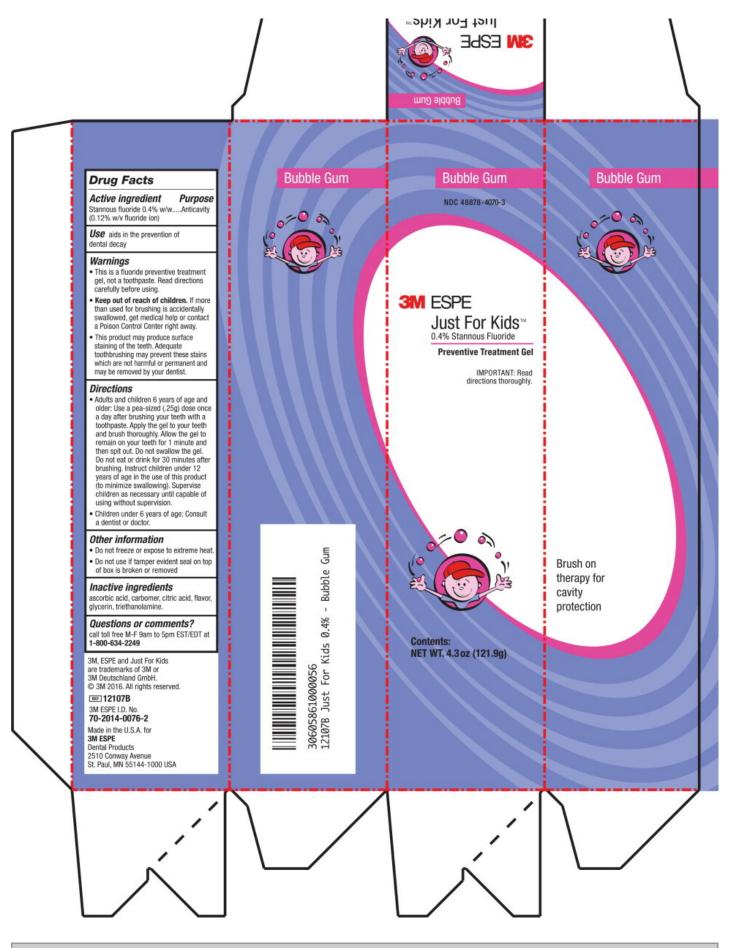
IMPORTANT: Read

directions thoroughly.

Contents:

NET WT. 4.3 oz (121.9 g)





JUST FOR KIDS

stannous fluoride gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:48878-4020
Route of Administration	ORAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
Stannous Fluoride (UNII: 3FTR44B32Q) (Fluoride Ion - UNII:Q80VPU408O)	Fluoride Ion	0.969 mg in 1 g		

Inactive Ingredients	
Ingredient Name	Strength
Ascorbic Acid (UNII: PQ6CK8PD0R)	
Carbomer Homopolymer Type B (Allyl Sucrose Crosslinked) (UNII: Z135WT9208)	
Anhydrous Citric Acid (UNII: XF417D3PSL)	
Glycerin (UNII: PDC6A3C0OX)	
Trolamine (UNII: 903K93S3TK)	

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

ı	Packaging				
4	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:48878- 4020-3	1 in 1 BOX	07/01/1997		
1	L	121.9 g in 1 TUBE; Type 0: Not a Combination Product			

Marketing Information				
Marketing Application Number or Monograph Marketing Start Marketing End Category Citation Date Date				
OTC Monograph Drug	M021	07/01/1997		

JUST FOR KIDS

stannous fluoride gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:48878-4070

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Stannous Fluoride (UNII: 3FTR44B32Q) (Fluoride Ion - UNII:Q80VPU408O)	Fluoride Ion	0.969 mg in 1 g

Inactive Ingredients	
Ingredient Name	Strength
Ascorbic Acid (UNII: PQ6CK8PD0R)	
Carbomer Homopolymer Type B (Allyl Sucrose Crosslinked) (UNII: Z135WT9208)	
Anhydrous Citric Acid (UNII: XF417D3PSL)	
Glycerin (UNII: PDC6A3C0OX)	
Trolamine (UNII: 9O3K93S3TK)	

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

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:48878- 4070-3	1 in 1 BOX	07/01/1997		
1		121.9 g in 1 TUBE; Type 0: Not a Combination Product			

Marketing Information			
Marketing Application Number or Monograph Marketing Start Marketing End Category Citation Date Date			
OTC Monograph Drug	M021	07/01/1997	

Labeler - Solventum US OpCo LLC (801390852)

Establishment			
Name	Address	ID/FEI	Business Operations
Dental Technologies, Inc.		148312838	MANUFACTURE(48878-4020, 48878-4070)