OMNI- stannous fluoride gel
3M ESPE Dental Products

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Active ingredient

Stannous fluoride 0.4% w/w (0.12% w/v 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, get medical help or contact a Poison Control Center right away.
- 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.

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**

Mint

NDC 48878-4061-3

3M ESPE

OMNI Gel™

0.4% Stannous Fluoride

Preventive Treatment Gel

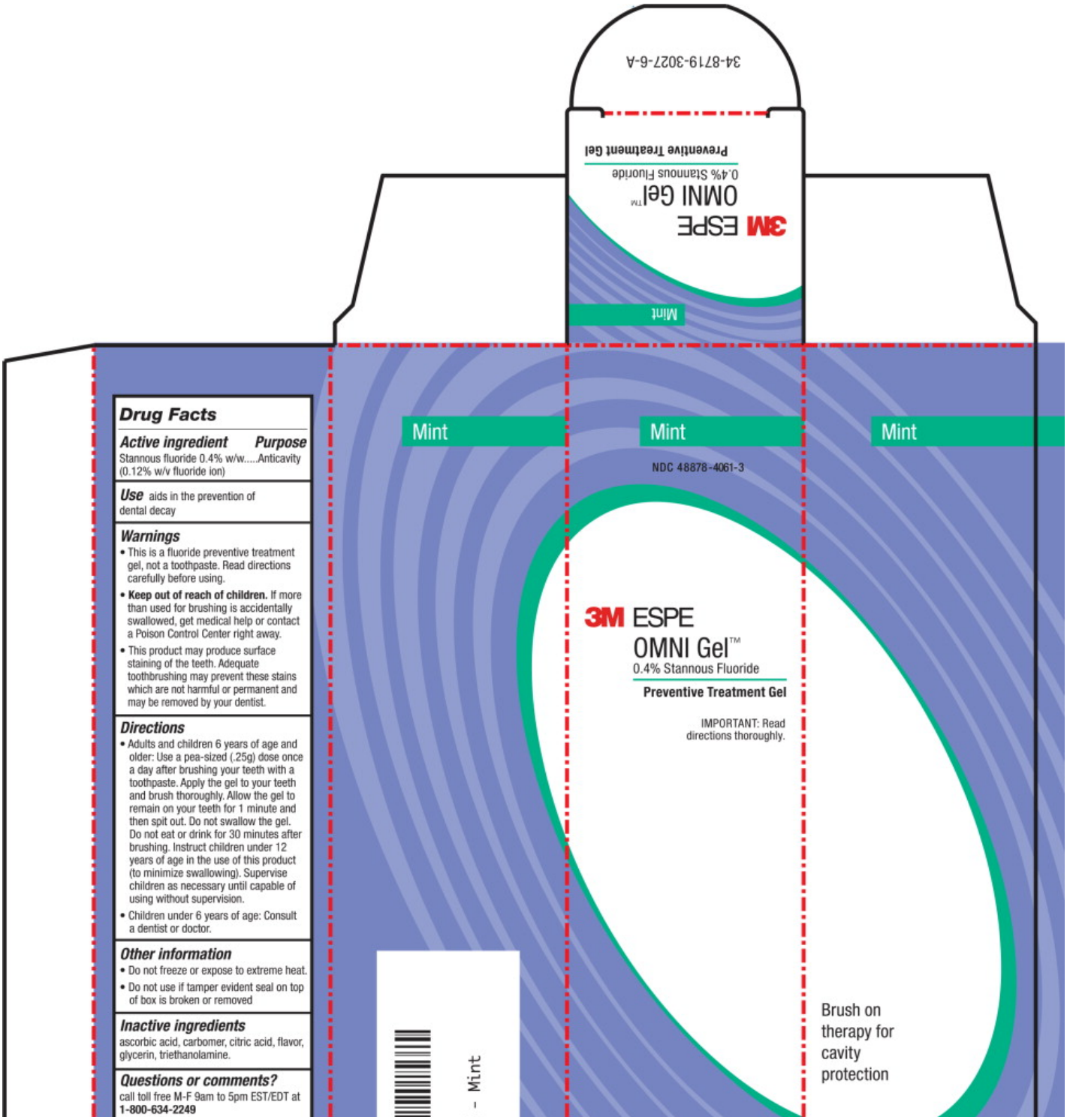
IMPORTANT: Read

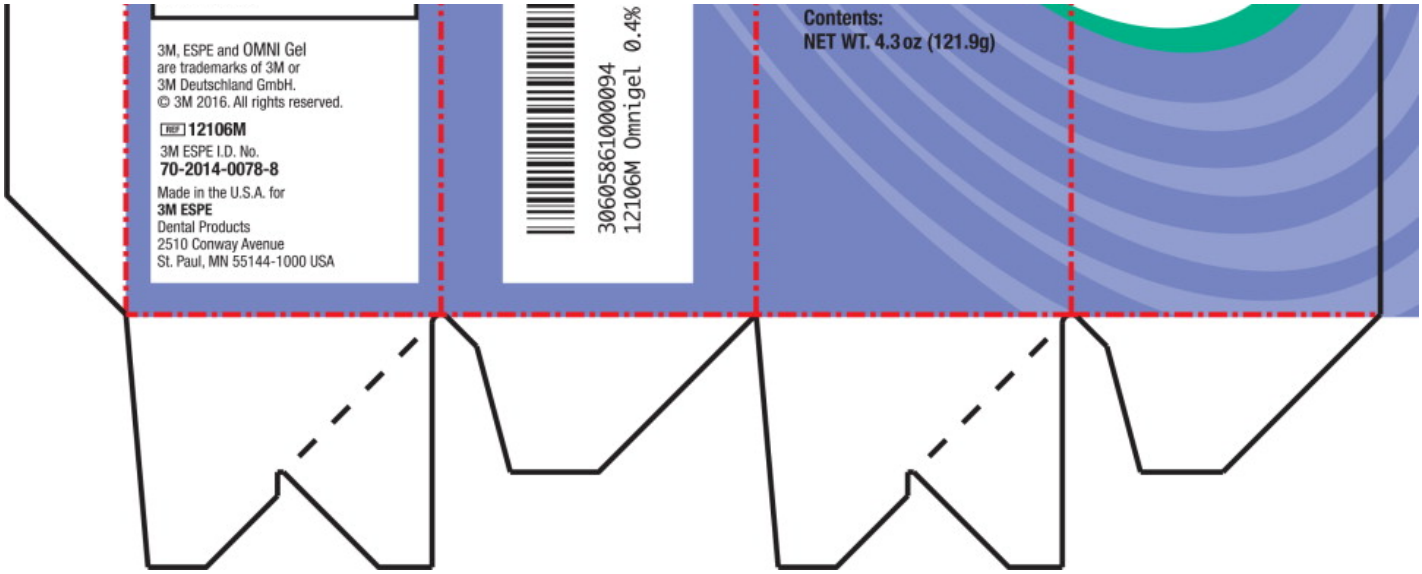
Directions thoroughly.

Contents:

1 Bottle

NET WT. 4.3 oz (121.9 g)





OMNI

stannous fluoride gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:48878-4061
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: 9O3K93S3TK)	

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:48878-4061-3	1 in 1 BOX	02/01/1998	

1		121.9 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	02/01/1998	

Labeler - 3M ESPE Dental Products (801390852)

Revised: 6/2019

3M ESPE Dental Products