

OMNI- stannous fluoride gel
Solventum US OpCo LLC

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**

Principle Display Panel

Mint

NDC 48878-4061-3

3M ESPE

OMNI Gel™

0.4% Stannous Fluoride

Preventive Treatment Gel

IMPORTANT: Read

Directions thoroughly.

Contents:

NET WT. 4.3 oz (121.9 g)

34-8719-3027-6-A

Preventive Treatment Gel
0.4% Stannous Fluoride
OMNI Gel™
3M ESPE

Mint

Mint

Mint

Mint

NDC 48878-4061-3

3M ESPE
OMNI Gel™
0.4% Stannous Fluoride
Preventive Treatment Gel

IMPORTANT: Read directions thoroughly.

Brush on therapy for cavity protection

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12106M
3M ESPE I.D. No.
70-2014-0078-8

Made in the U.S.A. for
3M ESPE
Dental Products
2510 Conway Avenue
St. Paul, MN 55144-1000 USA



3060586:1000094
12106M Omnigel 0.4% - Mint



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: PDC6A3C00X) | |
| 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 Drug | M021 | 02/01/1998 | |

