

CLINPRO 5000- sodium fluoride paste, dentifrice
Solventum US OpCo LLC

Principal Display Panel - CA Box Label

3M ESPE

Clinpro^{MC} 5000

Menthe-vanille

Dentifrice anticarie au

fluorure de sodium à 1,1 %

Formule de

diphosphate

tricalcique

novatrice

Offerte uniquement par 3M ESPE

Contenu : 1 tube POIDS NET : 113 g (4 oz)

NPN 80012416



Principal Display Panel - CA Tube Label

3M ESPE

Clinpro™ MC 5000

Vanilla Mint

Menthe vanilla

1.1% Sodium Fluoride **Anti-Cavity Toothpaste**

Dentifrice anticarie au fluorure de sodium à 1,1 %

NET WT 113 g (4 oz) / POIDS NET : 133 g (4 oz)

NPN 80012416

Innovative

**Tri-Calcium
Phosphate**

Exclusively from 3M ESPE

Formule de

diphosphate

tricalcique

innovante

Offerte uniquement par 3M ESPE

3M ESPE

Clinpro™ 5000

Vanilla Mint
Menthe vanille



1.1% Sodium Fluoride Anti-Cavity Toothpaste
Dentifrice anticarie au fluorure de sodium à 1,1 %

NET WT 113 g (4 oz) / POIDS NET : 113 g (4 oz)

NPN 80012416

Innovative
**Tri-Calcium
Phosphate**

Exclusively from 3M ESPE

Formule de
**diphosphate
tricalcique**

innovante

Offerte uniquement par 3M ESPE

INDICATIONS: Fluoride toothpaste for use in the prevention of dental cavities.

ACTIVE INGREDIENT: Sodium Fluoride (5000 ppm F⁻) 1.1% w/w (0.63% w/v fluoride ion).

INACTIVE INGREDIENTS: Water, Sorbitol, Hydrated Silica, Glycerin, Polyethylene-Polypropylene Glycol, Flavour, Polyethylene Glycol, Sodium Lauryl Sulfate, Titanium Dioxide, Carboxymethyl Cellulose, Sodium Saccharin, Tri-Calcium Phosphate.

DIRECTIONS FOR USE: This toothpaste is recommended for adults and children 6 years of age and older. To prevent swallowing of toothpaste, adult supervision is recommended for children under 12. Consult a healthcare practitioner before using with children under 6 years of age. Use once daily in place of a conventional toothpaste. Follow the instructions provided unless otherwise instructed by a healthcare practitioner.

1. Apply a thin ribbon or pea-sized amount of Clinpro™ 5000 1.1% Sodium Fluoride Anti-Cavity Toothpaste to a soft-bristled toothbrush, and brush teeth for two minutes.
2. After brushing, adults should expectorate. Children 6-16 years of age should expectorate and rinse mouth thoroughly with water. Your healthcare practitioner may recommend using only Clinpro™ 5000 Toothpaste or otherwise alter the directions.

WARNINGS: DO NOT SWALLOW. Keep out of reach of children under 6 years of age.

Read all instructions before using this product. Do not freeze or expose to extreme heat. Store at room temperature. If more product than amount normally used for brushing is accidentally swallowed, get medical help or contact a Poison Control Centre right away. Do not use if foil seal has been tampered with or broken.

Made in USA for
3M Canada
P.O. Box 5757
London, Ontario N6A 4T1
1-888-363-3685
www.3MESPE.ca

Fabriqué aux É.-U. pour :
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1 888 363-3685
www.3MESPE.ca

REF / N° de réf. : 12215

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34-8725-6467-8-A

Principal Display Panel - AU/NZ Box Label

PHARMACIST ONLY MEDICINE

KEEP OUT OF REACH OF CHILDREN

3M

Clinpro™ 5000

Sodium Fluoride 1.1% w/w

Vanilla Mint

Anti-Cavity Toothpaste

For use after professional recommendation.

Contains: 1 Tube NET WT 113g

AUST R 219455



Principal Display Panel - AU/NZ Tube Label

PHARMACIST ONLY MEDICINE

KEEP OUT OF REACH OF CHILDREN

3M

Clinpro™ 5000

Sodium Fluoride 1.1% w/w

Vanilla Mint

Anti-Cavity Toothpaste

For use after professional recommendation.

NET WT 113g

AUST R 219455

PHARMACIST ONLY MEDICINE

KEEP OUT OF REACH OF CHILDREN



Clinpro™ 5000

Sodium Fluoride 1.1% w/w



Vanilla Mint



Anti-Cavity Toothpaste

For use after professional recommendation.

NET WT 113g

AUST R 219455

INDICATIONS: Fluoride toothpaste for use after recommendation by a dental or medical professional, in the prevention of dental caries in high risk patients.

ACTIVE INGREDIENT: Sodium Fluoride 1.1% w/w or 11.05 mg/g (5000 ppm F-)

DIRECTIONS FOR USE: This toothpaste is recommended for adults and children 6 years of age and older. Use once daily in place of a conventional toothpaste. Follow these instructions unless otherwise instructed by a physician or dentist.

1. Apply a thin ribbon or pea-sized amount of Clinpro™ 5000 Sodium Fluoride 1.1% w/w Anti-Cavity Toothpaste to a soft-bristled toothbrush, and brush teeth for two minutes.
2. After brushing, adults should expectorate. Children 6-16 years of age should expectorate and rinse mouth thoroughly with water. Your physician or dentist may recommend using only Clinpro 5000 toothpaste or otherwise alter the directions.
3. For best results, do not eat or drink for 30 minutes after use.

PRECAUTIONS: DO NOT SWALLOW. If toothpaste is swallowed (more than used for normal brushing) obtain medical help or contact the Emergency Poisons Information Centre (in Australia 131 126 and in New Zealand 0800 764 766). If you are pregnant or may become pregnant, check with your doctor, dentist or pharmacist before using. Do not use this product in children 6 years of age or less. Read all instructions before using this product. Do not use if foil seal has been tampered with or broken. Store below 25°C.

Contains: saccharin

Made in USA for
3M New Zealand Limited
94 Apollo Drive, Rosedale
Auckland 0632
Ph 09 477 4040

Made in USA for
3M Australia Pty Limited
Building A, 1 Rivett Road
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Product Info: 136 136

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34-8725-6474-4-A

CLINPRO 5000

sodium fluoride paste, dentifrice

Product Information

| | | | |
|--------------------------------|-------------------------|---------------------------|----------------|
| Product Type | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:48878-3120 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|-------------|
| sodium fluoride (UNII: 8ZYQ1474W7) (fluoride ion - UNII:Q80VPU4080) | fluoride ion | 5 mg in 1 g |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| Water (UNII: 059QF0KO0R) | |
| Sorbitol (UNII: 506T60A25R) | |
| Silicon Dioxide (UNII: ETJ7Z6XBU4) | |
| Glycerin (UNII: PDC6A3C0OX) | |
| Polyethylene Glycol, Unspecified (UNII: 3WJQ0SDW1A) | |
| Sodium Lauryl Sulfate (UNII: 368GB5141J) | |
| Titanium Dioxide (UNII: 15FIX9V2JP) | |
| Carboxymethylcellulose Sodium (UNII: K679OBS311) | |
| Saccharin Sodium (UNII: SB8ZUX40TY) | |
| Tricalcium Phosphate (UNII: K4C08XP666) | |

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:48878-3120-1 | 1 in 1 BOX | 08/10/2009 | |
| 1 | | 113 g in 1 TUBE; Type 0: Not a Combination Product | | |
| 2 | NDC:48878-3120-2 | 1 in 1 BOX | 09/01/2017 | 11/30/2021 |
| 2 | | 113 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 |
|--------------------|--|----------------------|--------------------|
| Export only | | 08/10/2009 | |

