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

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use 3M™ ESPE™ Clinpro™ 5000 Anti-Cavity Toothpaste safely and effectively. See full prescribing information for Clinpro 5000 Anti-Cavity Toothpaste.
3M™ ESPE™ Clinpro 5000 1.1% Sodium Fluoride Anti-Cavity Toothpaste for oral use.
Initial U.S. Approval: None

INDICATIONS AND USAGE

Clinpro 5000 Anti-Cavity Toothpaste is indicated for use as part of a professional program for the prevention and control of dental caries. (1)

DOSAGE AND ADMINISTRATION

- Use once daily in place of conventional toothpaste unless instructed otherwise by a physician or dentist. (2)
- Apply a thin ribbon or pea-sized amount of Clinpro 5000 Anti-Cavity Toothpaste using a soft-bristled toothbrush and brush teeth for at least two minutes. (2)
- After brushing adults should expectorate. Children 6 to 16 years of age should expectorate and rinse mouth thoroughly with water. (2)

DOSAGE FORMS AND STRENGTHS

White toothpaste containing 1.1% sodium fluoride (3)

CONTRAINDICATIONS

Do not use in children under 6 years of age unless recommended by a dentist or physician. (4)

WARNINGS AND PRECAUTIONS

- Do not swallow. (5)
- Keep out of reach of children under 6 years of age. (5)
- Repeated ingestion of high levels of fluoride may cause dental fluorosis. (5)

ADVERSE REACTIONS

Allergic reactions and other idiosyncrasies have been rarely reported. (6)
To report SUSPECTED ADVERSE REACTIONS, contact 3M ESPE Dental Products Division at 1-800-634-2249 or *www.3MESPE.com*, or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch*
Revised: 1/2012

FULL PRESCRIBING INFORMATION: CONTENTS*

* Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

Clinpro 5000 Anti-Cavity Toothpaste is indicated for use as part of a professional program for the prevention and control of dental caries.

2 DOSAGE AND ADMINISTRATION

• Use once daily in place of conventional toothpaste unless instructed otherwise by a physician or dentist.

• Apply a thin ribbon or pea-sized amount of Clinpro 5000 Anti-Cavity Toothpaste using a soft-bristled toothbrush and brush teeth for at least two minutes.

• After brushing adults should expectorate. Children 6 to 16 years of age should expectorate and rinse mouth thoroughly with water.

• Follow these instructions or use as directed by a dental professional.

3 DOSAGE FORMS AND STRENGTHS

White toothpaste containing 1.1% sodium fluoride

4 CONTRAINDICATIONS

Do not use in children under 6 years of age unless recommended by a dentist or physician.

5 WARNINGS AND PRECAUTIONS

• DO NOT SWALLOW. If more than a pea-sized amount of Clinpro 5000 Anti-Cavity Toothpaste is swallowed, contact a medical or dental professional or a poison control center.

• Keep out of reach of children under 6 years of age.

• Repeated ingestion of high levels of fluoride may cause dental fluorosis. For this

reason, use in children with developing dentition requires special supervision to prevent swallowing. Prescribing dentists and physicians should consider risk of fluorosis when prescribing for use in children less than 6 years of age.

6 ADVERSE REACTIONS

Allergic reactions and other idiosyncrasies have been rarely reported.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Fluoride crosses the placenta in women and has been measured in cord blood, amniotic fluid, and serum of newborn children, but without a consistent correlation to maternal serum fluoride levels.[1,2] There are no data to indicate an increased susceptibility to fluorosis during pregnancy. Developmental studies were conducted by the National Toxicology Program, with sodium fluoride administered in the drinking water to pregnant rats and rabbits. No developmental toxicity was observed, even at doses that caused maternal toxicity. The No Adverse Effect Levels were about 29 mg/kg-day and 27 mg/kg-day for rabbits and rats, respectively.[3] There is no conclusive evidence of fluoride developmental effects in humans.[1,2]

The Institute of Medicine established a fluoride Upper Limit of 10 mg/day for pregnant women.[2]

Prescribing physicians and dentists should consider total fluoride exposure (dental care plus food, water and other sources) when prescribing the product for use in pregnant women or women who may become pregnant.

8.3 Nursing Mothers

An extremely small proportion of fluoride in drinking water is transferred to breast milk. The Institute of Medicine established a fluoride Upper Limit of 10 mg/day for nursing women.[2] Prescribing physicians and dentists should consider total fluoride exposure (dental care plus food, water and other sources) when prescribing the product for use in women who are nursing.

8.4 Pediatric Use

The primary adverse effects of fluoride are fluorosis of dental enamel and of the skeleton; these effects occur at exposures below those associated with other adverse health effects. The population most at risk for dental fluorosis is children during the period of tooth formation, i.e. from birth to 8 years of age. For this population, the Institute of Medicine established Fluoride Upper Limits of intake based on the risk of dental fluorosis. In populations with permanent dentition, skeletal fluorosis is the greatest risk from excessive fluoride. For this population the Institute of Medicine (IOM) established Fluoride Upper Limits based on the risk of skeletal fluorosis.[2]

Population	IOM Fluoride Upper Limit
Infants 0-6 months old	0.7 mg/day

Infants 7-12 months old	0.9 mg/day
Children 1-3 years old	1.3 mg/day
Children 4-8 years old	2.2 mg/day
Children > 8 years old	10 mg/day

Prescribing physicians and dentists should consider total fluoride exposure (dental care plus food, water and other sources) when prescribing the product for use in children.

8.5 Geriatric Use

No studies of Clinpro 5000 Anti-Cavity Toothpaste have been conducted to determine whether subjects aged 65 and over respond differently from younger subjects.

10 OVERDOSAGE

Ingestion of large amounts of fluoride may result in abdominal pain, stomach upset, nausea, vomiting, and diarrhea. These symptoms may occur at overdosages of 5 mg/kg of body weight. Fluoride doses of 16 mg/kg have been fatal.

Treatment Recommendations for Overdose of Clinpro 5000 Anti-Cavity Toothpaste[4]		
Ingested fluoride dose	Amount for 10 kg (22 pound) child*	Recommended action to take
Less than 5 mg/kg	This equals less than ½ ounce (or less than 3 teaspoons).	Do not induce vomiting. Give 1-2 glasses of milk and observe for symptoms of stomach upset. If symptoms persist more than a few hours, seek medical attention or contact a poison control center.
5 mg/kg or more	This equals about ½ ounce (about 1 tablespoon) or more.	Do not induce vomiting. Give 1-2 glasses of milk and seek medical attention or contact a poison control center.
15 mg/kg	This equals 1 ounce or ¼ of the tube.	Seek immediate medical attention. Do not induce vomiting. Give 1-2 glasses of milk.
*The amount to reach the fluoride dose will be proportionately larger with older children and adults. A thin ribbon or pea-sized amount of Clinpro 5000 Anti-Cavity Toothpaste weighs approximately 0.3 g and contains approximately 1.5 mg of fluoride ion. A 4 oz. tube contains 564 mg of fluoride ion.		

11 DESCRIPTION

Clinpro 5000 1.1% Sodium Fluoride Anti-Cavity Toothpaste is a self-applied fluoride dentifrice for the prevention of dental caries. Each gram contains 5 mg of fluoride ion in a neutral pH base, consisting of water, sorbitol, hydrated silica, glycerin, polyethylene-polypropylene glycol, flavor, polyethylene glycol, sodium lauryl sulfate, titanium dioxide, carboxymethyl cellulose, sodium saccharin and tri-calcium phosphate.

12 CLINICAL PHARMACOLOGY

Clinpro 5000 1.1% Sodium Fluoride Anti-Cavity Toothpaste aids in the prevention of tooth decay. Fluoride delivered from Clinpro 5000 inhibits the demineralization of sound teeth and enhances the remineralization (i.e., repair) of demineralized teeth. During tooth brushing, fluoride is taken up by teeth and dental plaque. Fluoride is taken up with calcium and phosphate by demineralized teeth resulting in an improved tooth structure than contains more fluoride and less carbonate than naturally occurring tooth structure and is more resistant to acid challenge. Additionally, calcium fluoride is formed on the crystal structure of teeth. As the pH of the mouth drops, fluoride is released from calcium fluoride and aids in the remineralization of teeth. Fluoride taken up into plaque alters the activity of cariogenic bacteria. Fluoride inhibits the process by which cariogenic bacteria metabolize carbohydrates resulting in less acid and adhesive polysaccharide production by the bacteria.

15 REFERENCES

1. National Research Council. Fluoride in drinking water: A scientific review of EPA's standards; National Academies Press 2006.
2. IOM. Dietary Reference Intakes: The essential guide to nutrient requirements. National Academies Press 2006.
3. Heindel JJ, et al. Developmental toxicity evaluation of sodium fluoride administered to rats and rabbits in drinking water. Fundam Appl Toxicol 1996;30(2):162-177.
4. Poisindex. Toxicologic Management – Fluoride. Thomson Micromedex.

16 HOW SUPPLIED/STORAGE AND HANDLING

Clinpro 5000 Anti-Cavity Toothpaste is supplied as a white dentifrice paste in a 4 oz. (113 gm) plastic tube (NDC 48878-3120-4, Vanilla Mint Flavor; NDC 48878-3130-4 Spearmint Flavor; NDC 48878-3140-4 Bubble Gum Flavor).

Storage

This product is designed to be stored and used at room temperature. Do not freeze or expose to extreme heat. See outer package for expiration date.

Manufactured for:
3M ESPE
Dental Products
2510 Conway Avenue
St. Paul, MN 55144-1000 USA
Revision date: 01/11/2012

Rx Only

Principal Display Panel – Box Label

3M ESPE

NDC 48878-3120-4

Clinpro™ 5000

Vanilla Mint

1.1% Sodium Fluoride

Anti-Cavity Toothpaste

Innovative

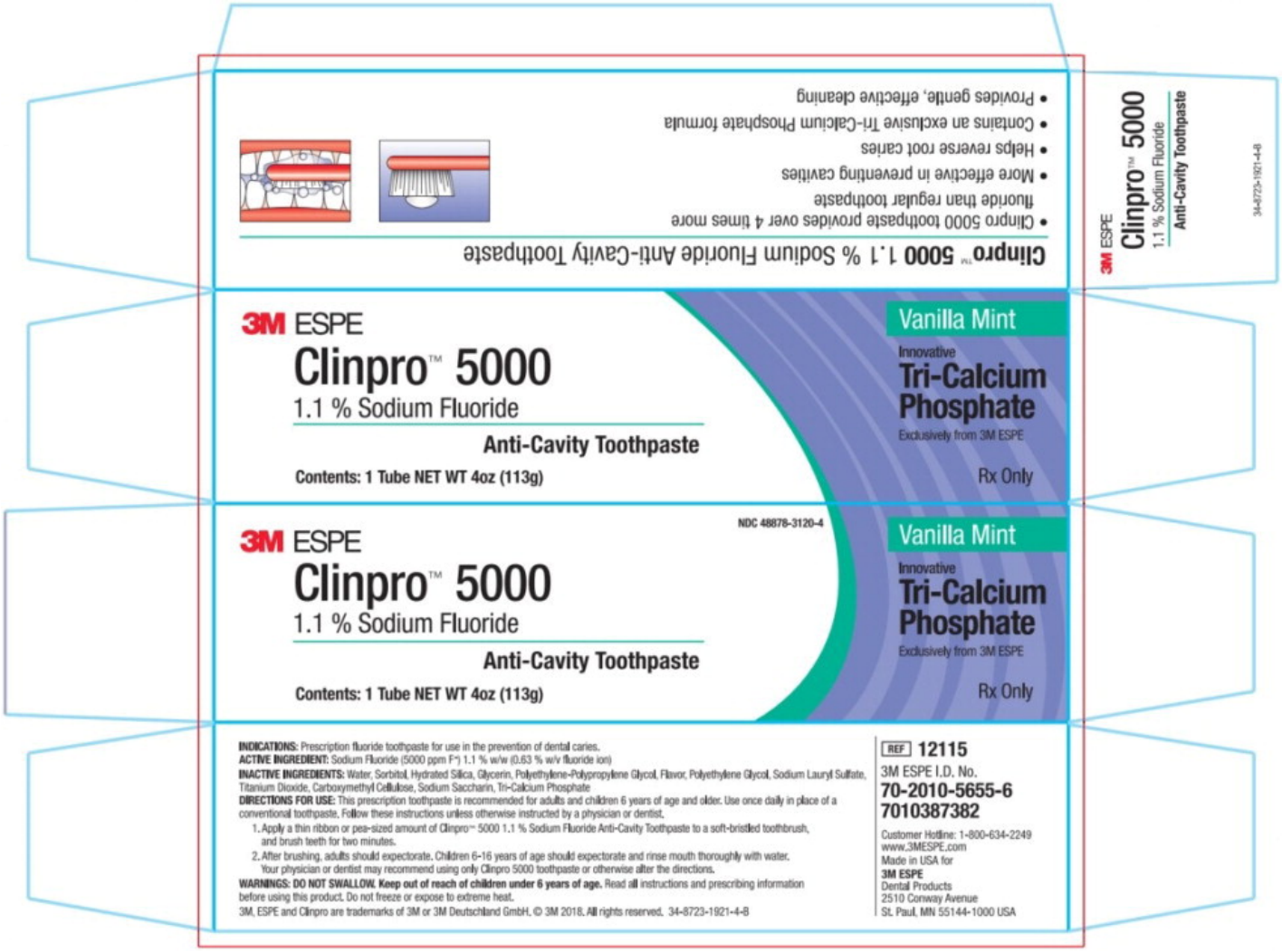
Tri-Calcium

Phosphate

Exclusively from 3M ESPE

Contents: 1 Tube NET WT 4oz (113g)

Rx Only



Principal Display Panel – Box Label

3M ESPE

NDC 48878-3130-4

Clinpro™ 5000

Spearmint

1.1% Sodium Fluoride

Anti-Cavity Toothpaste

Innovative

Tri-Calcium

Phosphate

Exclusively from 3M ESPE

Contents: 1 Tube NET WT 4oz (113g)

Rx Only

Principal Display Panel – Box Label

3M ESPE

NDC 48878-3140-4

Clinpro™ 5000

Bubble Gum

1.1% Sodium Fluoride

Anti-Cavity Toothpaste

Innovative

Tri-Calcium

Phosphate

Exclusively from 3M ESPE

Contents: 1 Tube NET WT 4oz (113g)

Rx Only

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:Q80VPU408O)	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: 3WQ0SDW1A)	
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:48878-3120-4	1 in 1 BOX	01/01/2009	
1		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
unapproved drug other		01/01/2009	

CLINPRO 5000

sodium fluoride paste, dentifrice

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:48878-3130
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
sodium fluoride (UNII: 8ZYQ1474W7) (fluoride ion - UNII:Q80VPU408O)	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: 3WQ0SDW1A)	
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	SPEARMINT (SPEARMINT)	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:48878-3130-4	1 in 1 BOX	10/15/2010	
1		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
unapproved drug other		10/15/2010	

CLINPRO 5000

sodium fluoride paste, dentifrice

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:48878-3140
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
sodium fluoride (UNII: 8ZYQ1474W7) (fluoride ion - UNII:Q80VPU408O)	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: 3WQ0SDW1A)	
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	BUBBLE GUM (BUBBLE GUM)	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:48878-3140-4	1 in 1 BOX	01/07/2011	
1		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
unapproved drug other		01/07/2011	

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