

3M Science.
Applied to Life.™

3M™ Clinpro™ 5000 Anti-Cavity Toothpaste (1.1% Sodium Fluoride)



NPN 80012416



Featuring functionalized tri-calcium phosphate – exclusively from 3M.

For patients at a moderate to high risk of caries, getting enough fluoride into their day can be a challenge. That's why we formulated 3M™ Clinpro™ 5000 Anti-Cavity Toothpaste: a clinically-proven treatment that fits into your patients' schedule.

Containing 1.1% Sodium Fluoride and our innovative functionalized tri-calcium phosphate (fTCP) ingredient, 3M™ Clinpro™ 5000 delivers more fluoride than toothpastes with a lower concentration of fluoride, as well as calcium and phosphate directly at the tooth surface to help strengthen and repair enamel.

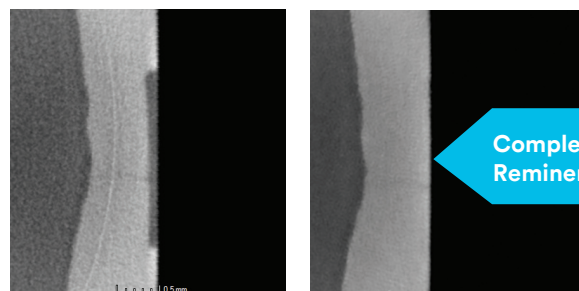
Key Advantages

- Contains 1.1% NaF (5000 ppm fluoride ion)
- Contains innovative functionalized tri-calcium phosphate (fTCP)
- Prevents, repairs and reverses white spot lesions
- Strengthens teeth with superior remineralization throughout lesions
- Optimized pH aids remineralization
- Creates acid-resistant mineral in dentin tubules
- Low-abrasive formula for gentle, effective cleaning of exposed root surfaces
- Delivers more fluoride to the tooth surface
- Recharges fluoride-releasing sealants and restorations
- Proven through 10 years of clinical usage



Clinically-Proven
Performance

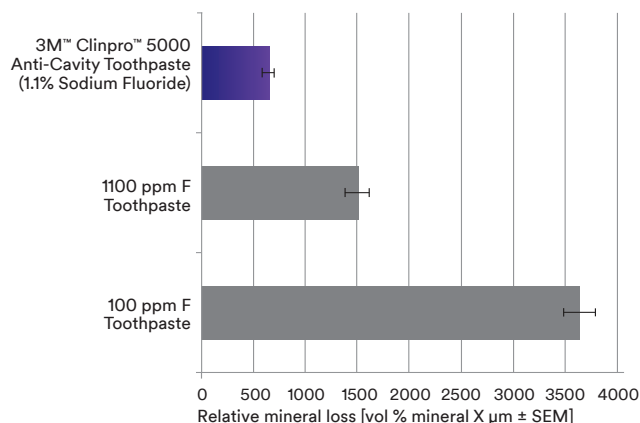
Remineralization of white spot lesions – 20 day pH cycling.¹



Baseline

20 d pH Cycling

Prevents Mineral Loss^{1,2}

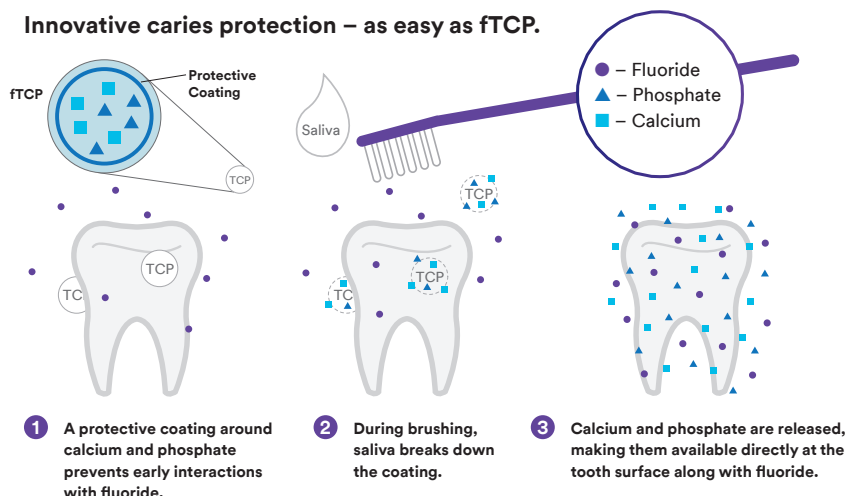


Our key ingredient to a healthier smile.

In traditional formulations, calcium and fluoride can combine prematurely in storage and render them less effective.

Our proprietary “smart” ingredient changes the game. It contains calcium and phosphate – the building blocks of healthy teeth, naturally found in saliva – and isolates them from fluoride until brushed on the teeth. Changing the way these critical minerals are delivered enhances their performance for superior remineralization and greater fluoride uptake.

Innovative caries protection – as easy as fTCP.



NPN 80012416

Ordering Information

Item #	Product Information
12215	3M™ Clinpro™ 5000 Anti-Cavity Toothpaste (1.1% Sodium Fluoride) – Vanilla Mint Flavour – 4 oz tube
12215SM	3M™ Clinpro™ 5000 Anti-Cavity Toothpaste (1.1% Sodium Fluoride) – Spearmint Flavour – 4 oz tube

3M™ Clinpro™ 5000

Anti-Cavity Toothpaste (1.1% Sodium Fluoride)

Highlights of Instructions for Use

3M™ Clinpro™ 5000 Anti-Cavity Toothpaste is indicated for use as part of a professional program for the prevention and control of dental caries.

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 3M™ 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.

Dosage Forms and Strengths

White toothpaste containing 1.1% sodium fluoride

Contraindications

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

Warnings and Precautions

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

Adverse Reactions

Allergic reactions and other idiosyncrasies have been rarely reported.

To report suspected adverse reactions, contact 3M Customer Care at 1-888-363-3685.

Use In Specific Populations

Pregnancy

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.

Nursing Mothers

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.

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 (IOM) 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 established Fluoride Upper Limits based on the risk of skeletal fluorosis.¹

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.

Geriatric Use

No studies of 3M™ Clinpro™ 5000 Anti-Cavity Toothpaste have been conducted to determine whether subjects aged 65 and over respond differently from younger subjects.

Overdosage

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

Treatment for Overdose of 3M™ Clinpro™ 5000 Toothpaste

Ingested fluoride dose	Amount for 10kg (22 pound) child*	Recommended action to take
Less than 5 mg/kg	This equals less than ¼ 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 centre.
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 centre.
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.

1. IOM. Dietary Reference Intakes: The essential guide to nutrient requirements. National Academies Press 2006.

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
St. Paul, MN 55144-1000 USA
Revision date: 01/11/2012

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¹ Data on file

² Inhibition of Demineralization and Promotion of Remineralization by 5000 ppmF Dentifrices. Featherstone, JDB.; et al. J. Dent. Res. 89 (Spec. Iss. B): 386, 2010 (www.dentalresearch.org).

3M.ca/Dental



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