

3M Science.
Applied to Life.™

Clinpro™ 5000

1.1% Sodium Fluoride
Anti-Cavity Toothpaste



**You'll see a
treatment ...
They'll see a
toothpaste.**

Clinpro™ 5000 1.1% Sodium Fluoride Anti-Cavity Toothpaste

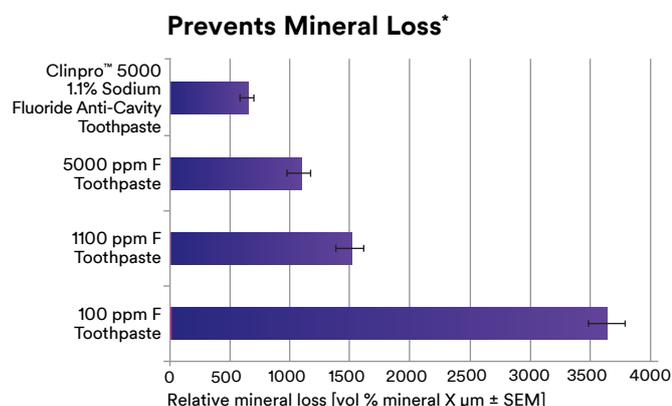
A proven formula that strengthens and repairs – without changing their routine.

Patients who are at high risk for caries are in need of preventive treatment, however, patient compliance can be a concern. When you prescribe Clinpro™ 5000 1.1% Sodium Fluoride Anti-Cavity Toothpaste from 3M, you are providing a high concentration sodium fluoride formulation that's easy for anyone to use. As part of a caries prevention program, Clinpro™ 5000 helps strengthen and repair enamel and is backed by over five years of clinical usage.



Protects against lesion progression

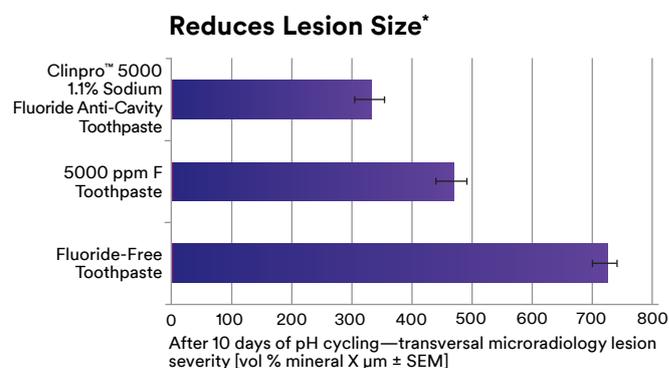
Clinpro™ 5000 toothpaste delivers strong protection against lesion initiation and progression by delivering high-quality mineral throughout the lesion—not just at the surface—to help prevent mineral loss.



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

Remineralises enamel to help repair early lesions

Clinpro™ 5000 toothpaste is proven to remineralise throughout the body of early lesions, resulting in smaller and less severe lesions after treatment.



Remineralisation potential of 5,000 ppm fluoride dentifrices evaluated in a pH cycling model. Amaechi BT, et al. J Dent Oral Hyg. 2(1), pp. 1-6, 2010.

*In-vitro study. Data on file.



Patient friendly...

- **Low abrasion:** Provides gentle, effective cleaning and is comfortable for patients to use even on exposed root surfaces.
- **One-step compliance:** Clinpro™ 5000 Anti-Cavity Toothpaste simply replaces your patient's current brushing regimen.
- **Patient friendly flavour:** Clinpro™ 5000 is available in a mild Vanilla Mint flavour, suitable for patients 6 years or older.
- **Convenient flip-top 113 g tube:** Lasts six months, so it's easy to renew at each appointment.

Clinpro 5000**:

- Strengthens teeth and repairs early lesions
- Proven remineralisation throughout the lesion
- Optimised pH aids remineralisation
- Creates acid-resistant, enamel-like remineralisation
- Mineralises and occludes dentine tubules
- Over 5 years clinical usage

** Claim data on file.

Remineralisation of patient dentine tubules from professional strength dentifrices.

This evaluation qualitatively explores the effects of prescription-strength topical NaF pastes on patent tubules in a pH cycling model comprising remineralisation and demineralisation phases. The results from this laboratory model demonstrated that Clinpro 5000 generates acid-resistant tubule occlusion, and is consistent with independent clinical results.

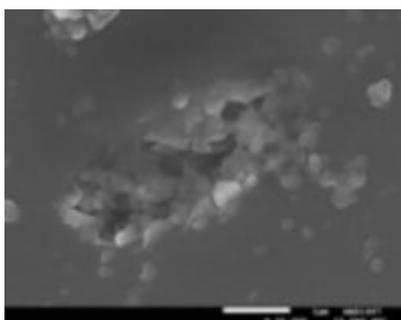


Figure 1. High magnification (20,000x) SEM image of dentine after remineralisation phase of *in vitro* pH cycling study. Representative images from dentin treated with Clinpro 5000. The white scale bars correspond to 1 µm.

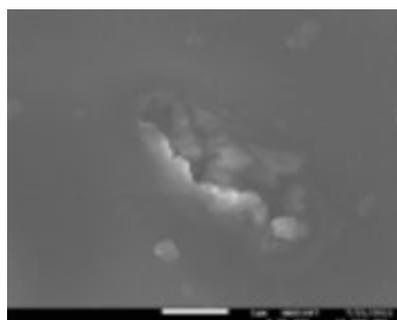


Figure 2. High magnification (20,000x) SEM image of dentine after remineralisation and subsequent citric acid challenges of *in vitro* pH cycling study. Representative images from dentin treated with Clinpro 5000. The white scale bars correspond to 1 µm.

Clinpro™ 5000

Vanilla Mint, anti-cavity toothpaste (Sodium fluoride)

HIGHLIGHTS OF PRESCRIBING INFORMATION INDICATIONS AND USAGE

DESCRIPTION

Clinpro 5000 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 purified water, sorbitol solution 70% non-crystallising, silicon dioxide, glycerol, poloxamer, flavour (Vanilla Mint), macrogol 600, sodium lauryl sulfate, titanium dioxide, carmellose sodium, saccharin sodium and TCP-SLS (modified calcium phosphate).

INDICATIONS

Clinpro 5000 is a fluoride toothpaste for use after recommendation by a dental or medical professional, in the prevention of dental caries in high risk patients.

CONTRAINDICATIONS

- Known allergic reactions or hypersensitivity to any of the stated ingredients.
- Not recommended for use in children under 6 years of age.

PRECAUTIONS

- Clinpro 5000 must not be swallowed. If more than a pea-sized amount of Clinpro 5000 is swallowed, contact a Poison Information Centre (in Australia 131 126 and in New Zealand 0800 764 766).
- 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. The risk of fluorosis should be considered if prescribing for use in children less than 6 years of age.

Use in Pregnancy

The Australian National Health and Medical Research Council (NHMRC) have established a Fluoride Upper Limit of 10 mg/day for pregnant women.

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.

Use in Lactation

An extremely small proportion of fluoride in drinking water is transferred to breast milk. The NHMRC has established a Fluoride Upper Limit of 10 mg/day for nursing women. 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.

Paediatric 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 NHMRC 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 NHMRC established Fluoride Upper Limits based on the risk of skeletal fluorosis.

Population

Population	NHMRC 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

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.

Clinpro 5000 is not recommended for use in children under 6 years of age.

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

Use in the Elderly

No studies have been conducted to determine whether subjects aged 65 and over respond differently from younger subjects.

INTERACTIONS WITH OTHER MEDICINES

There are no expected medicine interactions with topically applied fluoride.

ADVERSE EFFECTS

Allergic reactions and other idiosyncrasies have been rarely reported with the use of fluoride toothpastes.

OVERDOSAGE

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

A thin ribbon or pea-sized amount of Clinpro 5000 weighs approximately 0.3 g and contains approximately 1.5 mg of fluoride ion. A 113 g tube contains 564 mg of fluoride ion. Contact the Poisons Information centre (in Australia 131126 and in New Zealand 0800 764 766) for the most up-to-date treatment recommendations.

STORAGE CONDITIONS

Store below 25°C.

CLASSIFICATION SCHEDULE

Schedule 3 - Pharmacist Only Medicine

This is a summary of the prescribing information. For complete prescribing information, and dosage and administration guidelines, please visit www.3M.com.au/preventive or www.3M.co.nz/preventive

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Ordering Information

Item #	Product Information
12214	Clinpro™ 5000 1.1% Sodium Fluoride Anti-Cavity Toothpaste—Vanilla Mint Flavour – 113 g tube

For Prescribing Information and Consumer Medicine Information please visit:
www.3M.com.au/preventive
www.3M.co.nz/preventive



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Claims supported by data on file.

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