1 PRODUCT NAME

Clinpro 5000 anti-cavity toothpaste Vanilla Mint
Clinpro 5000 anti-cavity toothpaste Spearmint
Clinpro 5000 anti-cavity toothpaste Bubble Gum

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Thick white paste containing sodium fluoride (5000 ppm F ion) 1.1% w/w (0.63% w/v fluoride ion).

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, Spearmint or Bubble Gum), macrogol 600, sodium lauryl sulfate, titanium dioxide, carmellose sodium, saccharin sodium and TCP-SLS (modified calcium phosphate).

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Clinpro 5000 is a self-applied fluoride dentifrice presented as a thick white paste for the prevention of dental caries.

4 CLINICAL PARTICULARS

4.1 Therapeutic 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.

4.2 Dose and method of administration

Clinpro 5000 is recommended for adults and children 6 years of age and older, as part of a caries prevention program.

Use **Clinpro 5000** once daily in place of a conventional toothpaste unless instructed otherwise by a dentist or physician.

Apply a thin ribbon or pea-sized amount of **Clinpro 5000** to 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.

For best results, do not eat or drink for 30 minutes after use.

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

4.3 Contraindications

Known allergic reactions or hypersensitivity to any of the stated ingredients.

Not recommended for use in children under 6 years of age.

4.4 Special warnings and precautions for use

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

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	**NHMRC Fluoride Upper Limit**
Infants 0-6 months old*	1.2mg/day
Infants 7-12 months old*	1.8mg/day
Children 1-3 years old*	2.4mg/day
Children 4-8 years old*	4.4mg/day
Children > 8 years old	10 mg/day

*The NHMRC Fluoride Upper Limit levels for 0-8 year olds were updated in 2017. The following reference body weights were used when the 2017 Nutrient Reference Values for infants and young children aged 0-8 years were expressed in mg fluoride/day; 0-6 months 6kg, 7-12 months 9kg, 1-3 years 12kg, 4-8 years 22 kg.

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.

4.5 Interaction with other medicines and other forms of interaction

There are no expected medicine interactions with topically applied fluoride.

4.6 Fertility, pregnancy and lactation

Use in Fertility

No data available.

Use in 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. There are no data to indicate an increased susceptibility to fluorosis during pregnancy. Developmental studies were conducted by the US 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. There is no conclusive evidence of fluoride developmental effects in humans.

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.

4.7 Effects on ability to drive and use machines

The effects of this medicine on a person's ability to drive and use machines were not assessed as part of its registration.

4.8 Undesirable effects

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

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions CARMreport@health.govt.nz

4.9 Overdose

Ingestion of large amounts of fluoride may result in abdominal pain, stomach upset, nausea, vomiting, and diarrhoea. These symptoms may occur at overdosages 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 113g 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.

5 PHARMACOLOGICAL PROPERTIES

The molecular formula of sodium fluoride is NaF.
CAS 7681-49-4

Clinical Pharmacology
The fluoride delivered to the teeth from **Clinpro 5000** inhibits the demineralisation of sound teeth and enhances the remineralisation (i.e., repair) of demineralised teeth. During tooth brushing, fluoride is taken up by teeth and dental plaque. Fluoride is taken up with calcium and phosphate by demineralised teeth resulting in an improved tooth structure that 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 remineralisation of teeth. Fluoride taken up into plaque alters the activity of cariogenic bacteria. Fluoride inhibits the process by which cariogenic bacteria metabolise carbohydrates resulting in less acid and adhesive polysaccharide production by the bacteria.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Carmellose sodium
Glycerol
Hydrated silica
Macrogol 600
Poloxamer 407
Purified water
Saccharin sodium
Sodium lauryl sulfate
Sorbitol solution 70%
TCP-SLS
Titanium dioxide

Flavour – vanilla mint, spearmint, bubblegum

6.2 Incompatibilities

In the absence of compatibility studies, this medicine must not be mixed with other medicines.

6.3 Shelf life

Clinpro 5000 Vanilla Mint anticavity toothpaste 113g - 36 months
Clinpro 5000 Spearmint anticavity toothpaste 113g - 36 months
Clinpro 5000 Bubblegum anticavity toothpaste 113g - 24 months

Not all flavours may be marketed.

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

Laminate tube with flip top cap containing 113g of paste.

Available in Vanilla Mint, Spearmint and Bubble Gum flavours*.

*not all flavours may be marketed

6.6 Special precautions for disposal

Any unused medicine or waste material should be disposed of in accordance with local requirements.

7 MEDICINE SCHEDULE

Pharmacist Only Medicine

8 SPONSOR

KCI New Zealand Unlimited

Suite 1701, Level 17, PwC Tower

15 Customs Street West

Auckland Central

Auckland 1010

Telephone: 0800 808 182

9 DATE OF FIRST APPROVAL

19 December 2013

10 DATE OF REVISION OF THE TEXT

01 August 2024

SUMMARY TABLE OF CHANGES

Section changed	Summary of new information
2	Added excipient reference statement as per DS template
3	Added ‘presented as a’ to link statements previously from description and presentation sections
4.4	Updated NHMRC Fluoride Upper Limits values as per revised published guidelines as at March 2017
4.6	Added fertility statement as per DS template
4.7	Added statement as per DS template
4.8	Added reporting details for suspected adverse reactions as per DS template
6.1	Added full list of excipients as per TPDR
6.2	Added incompatibility statement as per DS template recommendation
6.3	Added shelf life as per TPDR and marketing status statement
6.5	Added reference: ‘not all flavours may be marketed’ as per DS template guidance
6.6	Added disposal statement as per DS template
8	Added sponsor telephone number as per DS template recommendation
9	Added date of first approval as per TPDR
4.8	Updated adverse event reporting in accordance with Medsafe updated guidance
8	Sponsor details updated 3M NZ Ltd removed and KCI NZ Unlimited added
10	Date of revision updated to 01August2024