

NAME OF THE MEDICINE

Clinpro 5000 Vanilla Mint, anti-cavity toothpaste
Clinpro 5000 Spearmint, anti-cavity toothpaste
Clinpro 5000 Bubble Gum, anti-cavity toothpaste
(Sodium fluoride)

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

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

PHARMACOLOGY

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 metabolize carbohydrates resulting in less acid and adhesive polysaccharide production by the bacteria.

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

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.

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	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.

DOSAGE AND 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.

OVERDOSAGE

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.

PRESENTATION AND STORAGE CONDITIONS

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

Laminate tube with flip top cap containing 113g of paste. Available in Vanilla Mint, Spearmint and Bubble Gum flavours.

Store below 25°C.

NAME AND ADDRESS OF SPONSOR

In Australia:

3M Australia Pty Limited
Building A
1 Rivett Road
North Ryde, NSW 2113.

In New Zealand:

3M New Zealand Limited
94 Apollo Drive
Rosedale
Auckland 0632.

POISON SCHEDULE OF THE MEDICINE

Schedule 3 - Pharmacist Only Medicine

DATE OF FIRST INCLUSION IN THE AUSTRALIAN REGISTER OF THERAPEUTIC GOODS (the ARTG):

22 January 2014

DATE OF MOST RECENT AMENDMENT: