# NEW ZEALAND DATA SHEET

## 1. PRODUCT NAME

NeutraFluor 5000 Plus
5000ppm Fluoride Professional Toothpaste
1.1% w/w Neutral Sodium Fluoride plus a mild cleaning system

## 2. QUANTITATIVE AND QUALITATIVE COMPOSITION

**Active Ingredient:** sodium fluoride 1.1% (w/w)

**Excipients:** Purified water, sorbitol, silicon dioxide, macrogol 600, potassium pyrophosphate, xanthan gum, flavour, sodium benzoate, sodium lauryl sulphate, sodium saccharin, brilliant blue FCF 42090.

## 3. PHARMACEUTICAL FORM

Toothpaste

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic Indications

Self-applied topical 1.1% w/w neutral sodium fluoride toothpaste for use as a dental caries preventive in individuals at high risk for caries. To be used as part of a preventive regimen recommended by a dental professional or doctor.

In individuals at high risk for caries, the use of a high concentration fluoride toothpaste as part of a preventive regimen prescribed by a dental professional is a rational approach to caries control. 1.1% sodium fluoride was first reported to provide significant protection against dental caries in the 1960's when it was applied in a mouth tray daily to school children[1-2]. NeutraFluor 5000 Plus is easily applied on a toothbrush and should be used daily in place of regular fluoride toothpaste unless otherwise instructed by a dental professional. More recent studies have shown its effectiveness in preventing dental caries in children with high caries experience, adults with root caries and patients with xerostomia[3-6]. As NeutraFluor 5000 Plus delivers fluoride topically to teeth and is intended for erupted teeth in adults and children over the age of ten, the increades fluoride dose should not contribute to fluorosis provided it is not used in an unsupervised manner in children under ten years of age.

**References:**

1. Englander HR, Keyes et al JADA 75: 638-644, 1967
2. Englander HR, et al; JADA 83:354-358, 1971.
3. Dreizen S et al; J Den Res56: 99-104, 1977
4. Cutress T et al; J Dent Child 59: 313-8, 1992
5. De Paola P; In Cariology for the 90's: 26-35p
6. ARCPOH; Aust.Dent. J 2006; 51(2):195-199

## 4.2 Dose and Method of Administration

1. Adults and children 10 years and older: a thin ribbon of NeutraFluor 5000 Plus should be applied to a soft toothbrush. Teeth should be brushed thoroughly for two minutes.
2. After use, spit out excess toothpaste. Refrain from eating, drinking or rinsing for 30 minutes.

## 4.3 Contraindications

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

## 4.4 Special Warnings and Precaution for Use

Not for systemic treatment. DO NOT SWALLOW. Not for use in children under 10 years unless recommended by a dentist or physician. If recommended for use in children under 10 years, parental supervision of brushing should be recommended. Prolonged daily ingestion may result in various degrees of dental fluorosis in children under 10 years; especially if the water fluoridation exceeds 0.6ppm, since younger children frequently cannot perform the brushing process without significant swallowing.

## 4.5 Interaction with Other Medicines and Other Forms of Interaction

There are no expected drug interactions with topically applied fluoride.

## 4.6 Fertility, Pregnancy and Lactation

***Use in Pregnancy:*** Category B.

It has been shown that fluoride crosses the placenta of rats, but only 0.01% of the amount administered is incorporated in foetal tissue. Animal studies (rats, mice, rabbits) have shown that fluoride is not a teratogen. Fluoride has been taken by a limited number of pregnant women of childbearing age, without an increase in the frequency of malformation or other direct or indirect harmful effect on the human foetus having been observed. Epidemiological studies conducted in areas with high levels of naturally fluoridated water showed no increase in birth defects. Heavy

exposure to fluoride during *in utero* development may result in skeletal fluorosis, which becomes evident in childhood.

***Use in Lactation***

It is not known if fluoride is excreted in breast milk. However many drugs are excreted in milk and caution should be exercised when products containing fluoride are administered to lactating women.

## 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.

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 https://pophealth.my.site.com/carmreportnz/s/.

## 4.9 Overdose

Accidental ingestion of large amounts of fluoride may result in acute burning in the mouth and sore tongue. Nausea, vomiting and diarrhoea may occur soon after ingestion (within 30 minutes) and are accompanied by salivation, haematemesis, and epigastric cramping abdominal pain. These symptoms may persist for 24 hours. If less than 5 mg fluoride/kg body weight has been ingested give calcium (eg milk) orally to relieve gastrointestinal symptoms and observe for a few hours. If more than 5 mg fluoride/kg body weight has been ingested give orally soluble calcium (eg milk. 5% calcium gluconate or calcium lactate solution) and seek immediate medical assistance. For accidental ingestion of more than 15mg fluoride /kg body weight, admit immediately to a hospital facility.

A treatment dose (a thin ribbon) of NeutraFluor 5000 Plus toothpaste contains approximately 2.5mg Fluoride.

Contact the New Zealand Poisons Information Centre on 0800 764 766 for specific treatment and recommendations.

## 5. PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic Properties

Frequent topical applications to the teeth with preparations having a relatively high fluoride content increase tooth resistance to acid dissolution and enhance penetration of the fluoride ion into tooth enamel.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of Excipients

Purified water, sorbitol, silicon dioxide, macrogol 600, potassium pyrophosphate, xanthan gum, flavour, sodium benzoate, sodium lauryl sulphate, sodium saccharin, brilliant blue FCF 42090.

### 6.2 Shelf Life

2 years

### 6.3 Special Precautions for Storage

Store below 25ºC.

### 6.4 Nature and Contents of Container

56g net weight tube.

## 7. MEDICINE SCHEDULE

Restricted Medicine

## 8. SPONSOR

Colgate-Palmolive Ltd
105 Carlton Gore Rd Newmarket, Auckland 1023
New Zealand

## 9. DATE OF FIRST APPROVAL

19 April 2001

## 10. DATE OF REVISION OF TEXT



31 December 2024

## SUMMARY OF CHANGES

| Section | Section changes | Summary of new information |
|---|---|---|
| 7 February 2019 | | |
| 1 | Product Name | New Section heading in compliance with new template for Data Sheet. No new information. |
| 2 | Quantitative and Quantitative Composition | New Section heading in compliance with new template for Data Sheet. No new information. |
| 3 | Pharmaceutical Form | New Section heading in compliance with new template for Data Sheet. No new information. |
| 4 | Clinical Particulars | New Section heading in compliance with new template for Data Sheet. No new information, other than<br>Section 4.1- Correction of typographical error from "increades" to "increased"<br>Section 4.7 - New information in compliance with new template for Data Sheet.<br>Section 4.7 - Retitled to **4.8 Undesirable Effects**<br>Section 4.8 - Retitled to **4.9 Overdose** and change in NZ Poisons information contact phone number. |
| 5 | Pharmacological Properties | New Section heading in compliance with new template for Data Sheet. No new information. |
| 6 | Pharmaceutical Particulars | New Section heading in compliance with new template for Data Sheet. No new information, other than inclusion of new Shelf life information. |
| 7. | Medicine Schedule | New Section heading in compliance with new template for Data Sheet. No new information. |
| 8. | Sponsor | New Section heading in compliance with new template for Data Sheet. Change in sponsor address. |
| 9. | Date of first approval | New Section heading in compliance with new template for Data Sheet. No new information. |

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| 10. | Date of revision of the text | New Section heading in compliance with new template for Data Sheet. Summary of changes presented as per date of revision of text. |
| 31 December 2024 | | |
| 4.8 | Undesirable effects | Change of URL for reporting adverse reactions to "https://pophealth.my.site.com/carmreportnz/s/" |
| 8 | Sponsor | Change in address to:<br>"105 Carlton Gore Rd<br>Newmarket Auckland 1023<br>New Zealand" |