# NEW ZEALAND DATA SHEET

## 1. PRODUCT NAME

NeutraFluor 5000 Sensitive
5000ppm Fluoride Professional Toothpaste
1.1% w/w Neutral Sodium Fluoride, 5% w/w Potassium Nitrate plus a mild cleaning system

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

**Active Ingredients:** Sodium Fluoride 1.1% w/w
Potassium Nitrate 5% w/w

**Excipients:** Water, Silicon Dioxide, Sorbitol, Macrogol 600, Sodium lauryl sulphate, Carrageenan, Flavour, Poloxamer, Cocamidopropyl betaine, sodium saccharin, Mica, Sodium hydroxide, Titanium dioxide, Brilliant blue FCF, Quinoline yellow.

## 3. PHARMACEUTICAL FORM

Toothpaste

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic Indications

Self-applied topical 1.1% w/w neutral sodium fluoride toothpaste with 5% w/w potassium nitrate for use as a dental caries preventive in individuals with sensitive teeth who are 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 Sensitive toothpaste 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 Sensitive toothpaste delivers fluoride topically to teeth and is intended for erupted teeth in adults and children over the age of twelve, the increased fluoride dose should not contribute to fluorosis provided it is not used in an unsupervised manner in children under six 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

Adults and children 12 years and older: a thin ribbon of NeutraFluor 5000 Sensitive toothpaste should be applied to a soft toothbrush. Teeth should be brushed thoroughly for two minutes.

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 precautions for use

Not for systemic treatment. DO NOT SWALLOW. Not for use in children under 12 years unless recommended by a dentist or physician. If recommended for use in children under 12 years, parental supervision of brushing should be recommended. Prolonged daily ingestion may result in various degrees of dental fluorosis in children under 6 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 authorization 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 http://nzphvc.otago.ac.nz/reporting/.

### 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 Sensitive 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.

With regular use, potassium nitrate has been proven to relieve the sensitivity of teeth by having a direct desensitising effect on the pulpal nerve fibres of the tooth, reducing the pain and sensitivity of the teeth.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Water, Silicon Dioxide, Sorbitol, Macrogol 600, Sodium lauryl sulphate, Carrageenan, Flavour, Poloxamer, Cocamidopropyl betaine, sodium saccharin, Mica, Sodium hydroxide, Titanium dioxide, Brilliant blue FCF, Quinoline yellow.

### 6.2 Shelf life

2 years

### 6.3 Special Precautions for Storage

Store below 25ºC.

### 6.4 Nature and Contents of Container

115 g net weight bottle.

## 7 MEDICINE SCHEDULE

Restricted Medicine

## 8 SPONSOR

Colgate-Palmolive Ltd
45 Knights Road
Lower Hutt
NZ

## 9 DATE OF FIRST APPROVAL

27 May 2010

## 10 DATE OF REVISION OF TEXT

28 June 2019

## SUMMARY OF CHANGES

| Section | Section changes | Summary of new information |
|---|---|---|
| 1 | Product Name | New section heading in compliance with new template for Data Sheet. No new information. |
| 2 | Quantitative and Qualitative 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: Section 4.1 – Correction of typographical error from |

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|---|---|---|
| | | "unsed" to "used" in the last statement.<br>Section 4.7 – New information in compliance with new template for Data Sheet.<br>Section 4.8 – Addition of last paragraph on the standard statements on the Reporting of Adverse Reactions. |
| 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 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. Sponsor address details updated. |
| 9 | Date of first approval | New section heading in compliance with new template for Data Sheet. No new information. |
| 10 | Date of revision of text | New section heading in compliance with new template for Data Sheet. Summary of changes presented as per date of revision of text. |