SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Sodium Fluoride 5000 ppm Toothpaste

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 g of toothpaste contains 5 mg fluoride (as sodium fluoride), corresponding to 5000 ppm fluoride.

Excipient(s) with known effect:
Propylene glycol
Sodium benzoate

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Toothpaste.
Blue paste.
For dental use

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Prevention of dental caries in adolescents and adults, particularly amongst patients at risk from multiple caries (coronal and/or root caries).

4.2 Posology and method of administration

Posology

Adults, adolescents and children aged 16 years and over

For use by persons aged 16 years of age and over only.

Brush carefully on a daily basis:
- apply a 2 cm ribbon onto your toothbrush for each brushing. 2 cm provides between 3 mg and 5 mg of fluoride.
- 3 times daily, after each meal.
- vertically, from the gum to the tip of the tooth.

Careful brushing takes approximately 3 minutes.

Paediatric population
The safety and efficacy of Sodium Fluoride 5000 ppm Toothpaste in children aged below 16 years has not yet been established.
Sodium Fluoride 5000 ppm Toothpaste is contraindicated in children and adolescents aged under 16 years (see section 4.3).

Method of administration
For dental use.
Not to be swallowed.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
Sodium Fluoride 5000 ppm Toothpaste is contraindicated in children and adolescents aged under 16 years.

4.4 Special warnings and precautions for use

This toothpaste has a high fluoride content. Therefore, the opinion of a dental specialist must be sought before the product is used.

An increased number of potential fluoride sources may lead to fluorosis. Before using fluoride medicines such as Sodium Fluoride 5000 ppm Toothpaste, an assessment of overall fluoride intake (i.e. drinking water, fluoridated salt, others fluoride medicines - tablets, drops, gum or toothpaste)

should be done. Fluoride tablets, drops, chewing gum, gels or varnishes and fluoridated water or salt should be avoided during use of Sodium Fluoride 5000 ppm Toothpaste.

When carrying out overall calculations of the recommended fluoride ion intake, which is 0.05 mg/kg per day from all sources, not exceeding 1 mg per day, allowance must be made for possible ingestion of toothpaste (each tube of Sodium Fluoride 5000 ppm Toothpaste contains 255 mg of fluoride ions).

This medicine contains 45 mg propylene glycol in each gram.

This medicine contains 1 mg benzoate salt in each gram. Benzoate salt may cause local irritation.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

4.6 Fertility, Pregnancy and lactation

Pregnancy
There is no adequate data from the use of Sodium Fluoride 5000 ppm Toothpaste in pregnant women. Studies in animals have shown reproductive toxicity of sodium fluoride only when administered at very high levels. Therefore, this toothpaste should not be used during pregnancy unless careful risk-benefit assessment has been carried out.

Breast-feeding
This toothpaste should not be used during lactation unless careful risk-benefit assessment has been carried out.

Fertility
There is no adequate data on the use of Sodium Fluoride 5000 ppm Toothpaste and effects on fertility. Studies in animals have shown reproductive toxicity of sodium fluoride only when administered at very high levels (see section 5.3).

4.7 Effects on ability to drive and use machines

Sodium Fluoride 5000 ppm Toothpaste has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

The following undesirable effects were assessed to be treatment-related and are classified according to the following convention: very common (≥1/10), common (>1/100 to <1/10), uncommon (>1/1,000 to ≤1/100), rare (>1/10,000 to ≤1/1000), very rare (≤1/10,000) or not known (cannot be estimated from the available data). Within each frequency grouping, undesirable effects are presented in decreasing order of seriousness.

System organ class	Frequency	Adverse reaction
Gastrointestinal disorders	Frequency not known	Burning oral sensation
Immune system disorders	Rare	Hypersensitivity reactions

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Acute intoxication: Fluoride
The toxic dose, i.e. the lowest dose at which symptoms of intoxication can be induced, is 5 mg fluoride per kg bodyweight.

Symptoms:
In very high doses, fluoride can have an acute toxic effect. Doses of several milligrams of fluoride per kg of body weight may cause nausea, vomiting, and diarrhoea. Tetany and convulsion can occur, as well as cardiovascular disorders. Increased risk of bone fracture and skeletal fluorosis (stiffness of joints and skeletal deformities) will only be observed in cases of very high chronic intake of fluoride.

Treatment:
Where a substantial quantity of the medicinal product is ingested accidentally, the patient will need to undergo gastric lavage immediately, or vomiting will need to be induced; calcium needs to be taken (large amount of milk), and the patient will require to be kept under medical observation for several hours.

Chronic intoxication: fluorosis
The dental enamel will take on a stained or speckled appearance once a fluoride dosage in excess of 1.5 mg per day is absorbed daily over several months or years, depending on the extent of overdose. This will be accompanied by increased enamel fragility in severe forms. Bone fluorosis (osteosclerosis) will only be seen where there is high chronic absorption of fluoride (over 8 mg daily).

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Stomatological preparations, Caries prophylactic agents.
ATC code: A01AA01.

The primary mode of the caries preventative action of fluoride is post-eruptive, i.e. topical. Systemic fluoride supplements are believed to act also mainly topically (e.g. during ingestion, via saliva).

There are three types of effect associated with fluoride:
- the inhibiting effect on demineralisation (lowering the enamel solubility in an acid environment);
- the promotion of remineralisation of enamel during the caries process;
- a bactericidal effect upon dental plaque organisms. This inhibits the proliferation of dental plaque bacteria and prevents formation of the acids that cause caries.

Fluoride alone is not enough to eliminate bacterial plaque, nor as a complete treatment for caries.

5.2 Pharmacokinetic properties

Sodium Fluoride 5000 ppm Toothpaste has a local, topical action on the teeth and so the route taken within the body does not apply. However, the following information has been included in case any toothpaste is accidentally ingested during treatment.

Absorption
Ingested fluride is converted to hydrofluoric acid. Peak concentrations are achieved within 30 – 60 minutes.

Distribution
The volume of distribution is 1 L / Kg. Fluoride ions are distributed to teeth and bones, and are not bound to plasma proteins.

Biotransformation
Ingested fluride is converted to hydrofluoric acid.

Elimination
The terminal half life is in the range 2 – 9 hours. Fluoride ions are excreted mainly in urine, but small amounts may also be excreted in faeces and sweat. It is not known in which form.

5.3 Preclinical safety data

Preclinical data reveal no special hazard for humans beyond the information included in other sections of the SPC. After oral administration of sodium fluoride to mice, rats and rabbits reproductive and feto-toxic effects were observed only at high dose levels.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sorbitol solution (non-crystallising)
Silicas (precipitated)
Macrogol 600
Tetrapotassium pyrophosphate
Sodium benzoate (E211)
Sodium lauryl sulfate
Carmellose sodium
Spearmint flavouring (containing Propylene glycol (1520), L-Carvone and Spearmint oil)

Mint flavouring (containing Propylene glycol, Mentha piperita, Mentha arvensis, Anethol and Spearmint oil)
Saccharin sodium
Brilliant Blue FCF
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years unopened.

Once opened use within 6 months.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

51g polyethylene/copolymer/aluminium/copolymer/polyethylene laminated tube with a polypropylene screw closure. The tube is packed inside an outer carton.
Pack sizes: 1 x 51 g tube or 3 x 51 g tubes.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Alissa Healthcare Research Limited
Unit 5, Fulcrum 1,
Solent Way, Whiteley,
Fareham, Hampshire
United Kingdom
PO15 7FE

8 MARKETING AUTHORISATION NUMBER(S)

PL 30322/0048

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

04/03/2025

10 DATE OF REVISION OF THE TEXT

04/03/2025