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 (sodium fluoride 1.1%w/w)

Excipient(s) with known effect:

Sorbitol solution (non-crystallising)…….56%w/w

Sodium benzoate…….0.1% w/w

Propylene glycol…….....2.35%w/w

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Toothpaste

For dental use

A blue colour smooth semisolid homogenous paste.

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

Paediatric population:

Sodium Fluoride 5000 ppm Toothpaste is contraindicated in children and adolescents aged under 16 years, see section 4.3.

Adult and adolescents and children aged 16 years or more:

To be used three times daily, after each meal, while brushing the teeth.

Brush carefully, on a daily basis, three times daily, following each meal:

- Apply a 2 cm ribbon of toothpaste onto the toothbrush for each brushing. A 2 cm ribbon provides between 3 mg and 5 mg of fluoride.
- Brush teeth vertically, from the gum to the tip of the teeth
- Careful brushing takes approximately three minutes

Not to be swallowed

Method of administration:

For dental use

4.3 Contraindications

This medicinal product must not be used in cases of hypersensitivity of 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 under 16 years of age, see section 4.2.

4.4 Special warnings and precautions for use

This toothpaste has 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, 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 Toothpaste.

When carrying out overall calculations of the recommended fluoride ion intake, which is 0.05mg/kg per day from all sources, not exceeding 1mg per day, allowance

must be made for possible ingestion of toothpaste (each tube of Sodium Fluoride 5000 ppm Toothpaste contains 255mg of fluoride ions).

It is important to control the use of sodium fluoride toothpaste in patients with chronic renal insufficiency, to avoid a risk of fluorosis.

This product contains sodium benzoate. Sodium benzoate is a mild irritant to the skin, eyes and mucous membrane.

This product contains sorbitol solution. Patients with rare hereditary problems of fructose intolerance should not take this medicine.

This product contains propylene glycol. Propylene glycol may cause skin 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 (see section 5.3). Therefore this toothpaste should not be used during pregnancy unless careful risk – benefit assessment has been carried out.

Breast-feeding

There is no adequate data from the use of Sodium Fluoride 5000 ppm Toothpaste in lactating women, and it is unknown if fluoride is excreted in breast milk. Therefore 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

Gastrointestinal disorders:

Frequency not known (cannot be estimated from the available data): burning oral sensation

Immune system disorders:

Rare (≥1/10,000 to <1/1,000): 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 the Yellow Card Scheme at: 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 5mg fluoride per kg body weight.

Such intoxication appears in the form of digestive problems: vomiting, diarrhoea, abdominal pain. In extremely rare cases, it can prove fatal. 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 need 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 1.5mg 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 8mg daily).

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: 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 swallowed during treatment.

Absorption

Ingested fluoride 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 fluoride 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 foeto-toxic effects were observed only at high dose levels.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Benzoate (E211)

Tetra Potassium Pyrophosphate

Sorbitol Solution (70 per cent) (Non-crystallising)

Precipitate Silica

Macrogol 600

Carmellose Sodium

Sodium Lauryl Sulphate

Saccharin Sodium

Brilliant Blue FCF (E133)

Spearmint Flavour No. 1 (propylene glycol)

Mint Flavour (propylene glycol)

Purified Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 Months

In use shelf-life: 6 months

6.4 Special precautions for storage

Do not store above 25ºC.

6.5 Nature and contents of container

51g of toothpaste filled in white coloured lami tube fitted with white coloured cap enclosed in an outer carton.

6.6 Special precautions for disposal

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

7 MARKETING AUTHORISATION HOLDER

DAWA Limited

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United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 30684/0272

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

27/01/2021

10 DATE OF REVISION OF THE TEXT

21/02/2025