# SUMMARY OF PRODUCT CHARACTERISTICS

## 1 NAME OF THE MEDICINAL PRODUCT

Sodium Fluoride 2800 ppm Toothpaste

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 g of toothpaste contains 2.8 mg fluoride (as sodium fluoride), corresponding to 2800 ppm fluoride, (sodium fluoride 0.619% w/w).

Excipient(s) with known effect

Sodium benzoate…….. 0.1% w/w

Sorbitol solution (non-crystalizing)……..23.1%w/w

Propylene glycol……..…..0.125%w/w

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Toothpaste.

For dental use

A white colour smooth semisolid homogenous paste.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic indications

For the prevention and treatment of dental caries (coronal and root) for adolescents and children aged over 10 years old.

### 4.2 Posology and method of administration

**Posology**

*Paediatric population*:

Sodium Fluoride 2800 ppm Toothpaste is contraindicated in children aged under 10 years, see section 4.3.

*Adolescents and children aged 10 years or more*:

To be used daily instead of normal toothpaste.

- Apply a 1 cm ribbon of toothpaste onto the toothbrush for each brushing
- Brush teeth vertically, from the gum to the tip of the teeth
- Careful brushing takes approximately one minute
- Spit out after use
- For best results do not drink or rinse for 30 minutes

Not to be swallowed

**Method of administration**

For dental use

## 4.3 Contraindications

Hypersensitivity to the active substance(s) or to any of the excipients listed in section 6.1.

Individuals with known sensitivities should consult their dentist before using.

Not to be used in children under 10 years old.

## 4.4 Special warnings and precautions for use

Not to be swallowed.

An increased number of potential fluoride sources may lead to fluorosis. In order to prevent the accumulation of fluoride, the total fluoride intake must be assessed before this fluoride toothpaste is used.

When carrying out overall calculations of the recommended fluoride ion intake, which is 0.05 mg/kg body weight per day from all sources, not exceeding 1 mg per day, allowance must be made for possible ingestion of toothpaste (each 75ml tube of Sodium Fluoride 2800 ppm Toothpaste contains 280 mg of fluoride ions).

This product contains propylene glycol. Propylene glycol may cause skin irritation.
This product contains Sodium benzoate. Sodium benzoate is a mild irritant to the skin, eyes and mucous membrane.

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

Paediatric population

This product should not be used by children aged under ten years, see sections 4.2 and 4.3.

## 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

Epidemiological studies in humans indicate that fluoride has no adverse effects in pregnancy or on the health of the foetus or newborn child.

No effects during pregnancy are anticipated, since systemic exposure to Sodium Fluoride is negligible.
Sodium Fluoride 2800 ppm Toothpaste can be used during pregnancy.

Breast-feeding

No effects on the breastfed newborn/infant are anticipated since the systemic exposure of the breast-feeding woman to Sodium Fluoride is negligible.
Sodium Fluoride 2800 ppm Toothpaste can be used during breast-feeding.

Fertility

There is no adequate data on the use of Fluoride 2800 ppm Toothpaste and the 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 2800 ppm Toothpaste has no or negligible influence on the ability to drive or 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

This product is toothpaste in which the active ingredient is Sodium Fluoride present at a level of 0.619% w/w which corresponds to 280 mg fluoride per 100 g paste.

Sodium fluoride applied topically after tooth eruption reduces caries by inhibiting demineralisation and promoting remineralisation of the tooth surface. It is effective on both enamel and exposed dentine.

## 5.2 Pharmacokinetic properties

Fluoride 2800 ppm Toothpaste has a local, topical action on the teeth and so the route taken within the body does not apply. This product is not intended to be swallowed and therefore only minimal systemic exposure is expected. However, the following information has been included in case any toothpaste is accidentally ingested 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

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential and toxicity to reproduction and development.

# 6 PHARMACEUTICAL PARTICULARS

## 6.1 List of excipients

Glycerol

Sodium benzoate (E211)

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

Precipitated Silica

Macrogol 600

Sodium Lauryl Sulphate

Carmellose Sodium

Mint Flavour (Propylene glycol)

Titanium Dioxide (E171)

Saccharin Sodium

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

75 ml of toothpaste filled in white coloured lami tube fitted with white coloured flip top 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

5 Sandridge Close,

Harrow, Middlesex,

HA1 1XD,

United Kingdom

## 8 MARKETING AUTHORISATION NUMBER(S)

PL 30684/0271

## 9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

27/01/2021

## 10 DATE OF REVISION OF THE TEXT

21/02/2025