# SUMMARY OF PRODUCT CHARACTERISTICS

## 1 NAME OF THE MEDICINAL PRODUCT

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.

Excipients with known effect:

Sorbitol and sodium benzoate

For full list of excipients, see section 6.1

## 3 PHARMACEUTICAL FORM

Toothpaste
A blue colored, opaque smooth gel with characteristic odour and taste.
For dental use.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic indications

Fluoride 5000 ppm toothpaste is indicated in adults and adolescents aged 16 years and over.
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 and children over 16 years old*:
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.
*Paediatric population:*
Fluoride 5000 ppm Toothpaste is contraindicated in children and adolescents aged under 16 years, see section 4.3.
Method of Administration:
For dental use

## 4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
Not to be used in children and adolescents under 16 years of age.

## 4.4 Special warnings and precautions for use

Not to be swallowed.
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. In order to prevent the accumulation of fluoride, the total fluoride intake must be assessed before this fluoride toothpaste is used. Fluoride tablets, drops, chewing gum, gel or varnishes, and fluoridted water or salt should be avoided during use of Fluoride 5000 ppm Toothpaste.

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 5 gm tube of Fluoride 5000 ppm Toothpaste contains 225 mg of fluoride ions).

Other Excipients:
This product contains Sorbitol. Patients with rare hereditary problems of fructose intolerance should not take this medicine.

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

## 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 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 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 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

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

## 4.8 Undesirable effects

*Immune system disorders:*
Rare (> 1 / 10,000, < 1 / 1,000): hypersensitivity reactions.
*Gastrointestinal disorders*:
Frequency not known (cannot be estimated from the available data): burning oral sensation.

**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 of the medicinal product. Healthcare professionals are asked to report any suspected

adverse reactions via the 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:*
The toxic dose, i.e the lowest dose at which symptoms of intoxication can be induced, is 5 mg 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.
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

*Pharmaco-therapeutic group:* caries prophylactic agents
*ATC-code:* A01AA01
The primary mode of the caries preventative action of fluoride is post-eruptive, i.e topical action. Systemic fluoride supplements are believed also to act mainly topically (i.e 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 results in inhibition of 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

Fluoride 5000 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. Peal 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.
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

Glycerol E422
Sorbitol, liquid (non-crystallising) E420
Brilliant blue (E133)
Carmellose Sodium
Sodium Saccharine
Sodium Benzoate E211
Macrogols 600
Dental type silicas
Tetra Potassium Pyrophosphate
Sodium laurilsulfate
Flavour mint SC
Purified water

### 6.2 Incompatibilities

None known

### 6.3 Shelf life

3 years unopened
6 months after opening.

### 6.4 Special precautions for storage

This product requires no special storage conditions.

### 6.5 Nature and contents of container

Polypropylene / aluminium / polyethylene laminated tube with a polypropylene screw cap.
Pack sizes: 1 x 51 g tube.

### 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

QP Services Ltd
46 High Street
Yatton, Bristol
Somerset
BS49 4HJ
United Kingdom

## 8 MARKETING AUTHORISATION NUMBER(S)

PL 29498/0010

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

15/05/2025

## 10 DATE OF REVISION OF THE TEXT

08/07/2025