SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Fluoritop® LF 2800 ppm Fluoride Toothpaste

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

<u>Excipients with known effect:</u>
Sorbitol and Sodium benzoate
For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Toothpaste

A white homogenous paste.

For dental use.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Fluoritop 2800 ppm toothpaste is indicated for the prevention and treatment of dental caries (coronal and root) in adolescents and children over 10 years.

4.2 Posology and method of administration

Posology:

Paediatric population:

Fluoritop 2800 ppm Toothpaste is contraindicated in children aged less than 10 years, see section 4.3.

Adolescents and children over 10 years old:

Use daily instead of the normal toothpaste.

The usual dosage is to apply a 1 cm line of paste across the head of a toothbrush and brush the teeth thoroughly for one minute morning and evening. 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 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 75 ml tube of Fluoride 2800 ppm Toothpaste contains 280 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

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. Fluoritop 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.

Fluoritop Toothpaste can be used during breast-feeding.

Fertility

There is no adequate data on the use of Fluoritop 2800 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

Not applicable

4.8 Undesirable effects

Immune system disorders:

Rare (> 1 / 10,000, < 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 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

4.9 Overdose

Acute Intoxication:

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:

Treatment and management should be symptomatic.
In case of mild gastrointestinal overdose symptoms a small glass of milk to drink should be given to bind fluoride ion.
It should be noted that gut decontamination is contraindicated. Charcoal is of no benefit.

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

This product is a tooth paste 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 toothpaste.

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

Fluoritop 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

Carmellose Sodium

Sodium Saccharine

Sodium Benzoate E211

Macrogols 600

Dental type silicas

Titanium Dioxide E171

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

75 ml polypropylene / aluminium / polyethylene laminated tube with a polypropylene flip-top cap.

Pack sizes: 1 x 75ml 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

Special Concept Development (UK) Limited T/A Rx Farma.

Colonial Way,

Watford WD24 4YR,

United Kingdom.

8 MARKETING AUTHORISATION NUMBER(S)

PL 36722/0076

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

08/04/2025

10 DATE OF REVISION OF THE TEXT

25/07/2025