SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Fluoride 2800 ppm 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.

Excipient(s) with known effect:

Sorbitol solution (non-crystallising)

Propylene glycol

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Toothpaste.

For dental use.

Smooth, white coloured paste with the odour and taste of spearmint.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Fluoride 2800 ppm Toothpaste is indicated in adolescents, and children aged 10 years and over.

Prevention and treatment of dental caries (coronal and root) adolescents and children aged ten years or more.

4.2 Posology and method of administration

Posology

Paediatric population:

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 the normal toothpaste.

Brush carefully and thoroughly, for one minute, morning and evening:

- 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.

For oromucosal use only.

4.3 Contraindications

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

Use by children aged under ten years, see section 4.2.

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).

This product contains propylene glycol. Propylene glycol may cause skin irritation.

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

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

Epidemiological studies in humans indicate that fluoride has no adverse effects in pregnancy or on the health of the foetus or new born child. Fluoride 2800 ppm Toothpaste can be used during pregnancy and lactation.

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 2800 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.

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 national reporting system, the Yellow card scheme at: www.mhra.gov.uk/yellowcard.

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 induceed; calcium needs tyo 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: caries prophylactic agents

ATC code: A01AA01

This product is a 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 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

Fluoride 2800 ppm FluorideTtoothpaste 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 fluride 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 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

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

After oral administration of sodium fluoride to mice, rates and rabbits, reproductive and foeto–toxic effects were observed only at high dose levels.

The total amount of fluoride in a 75 ml tube of Fluoride 2800 ppm Toothpaste is about 620 mg which equates to 280 mg fluoride. This is within the acceptable limits for the amount to be supplied at one time for safety purposes.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sorbitol solution (non-crystallising), E420

Glycerol, E422

Dental type silica (precipitated), E551

Macrogol 600, E1521

Sodium laurilsulphate

Carmellose sodium, E466

Sodium saccharin, E954

Titanium dioxide, E171

Mint flavour (947093 Optamint Spearmint) containing menthol, propylene glycol, spearmint oil, carvone, anethol, ethyl maltol, vanillin

Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Thirty six (36) months 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

Polyethylene/copolymer/aluminium/copolymer/polyethylene laminated tube with a polypropylene flip top closure. 75ml.

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

Morningside Healthcare Ltd,

115 Narborough Road,

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8 MARKETING AUTHORISATION NUMBER(S)

PL 20117/0239

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10/12/2014

10 DATE OF REVISION OF THE TEXT

22/07/2015