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.

Excipient(s) with known effect:

Sodium benzoate

Sorbitol solution (non-crystallising)

Propylene glycol

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Toothpaste.

For dental use.

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

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

Paediatric population:

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.

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 and adolescents aged under sixteen years, see section 4.2.

4.4 Special warnings and precautions for use

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 ever 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 51 g tube of Fluoride 5000 ppm Toothpaste contains 225 mg of fluoride ions).

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.

Paediatric population

This product should not be used by children and adolescents aged under sixteen 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

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

Gastrointestinal disorders:

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

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 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

Pharmacotherapeutic 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. 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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sorbitol solution (non-crystallising), E420

Dental type silica (precipitated), E551

Macrogol 600, E1521

Tetrapotassium pyrophosphate, E340

Xanthan gum, E415

Sodium benzoate, E211

Sodium laurilsulphate

Spearmint flavouring (Optamint 948800) containing menthol, propylene glycol, carvone, spearmint oil, peppermint oil, anethol, and vanillin

Saccharin sodium, E954

Brilliant Blue FCF, E133

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. 51g.

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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LE3 0PA,

United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 20117/0240

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10/12/2014

10 DATE OF REVISION OF THE TEXT

22/07/2015