PROFESSIONAL INFORMATION

SCHEDULING STATUS

S1

1. NAME OF THE MEDICINE

Duraphat® 5000 ppm Fluoride Toothpaste (Toothpaste)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 g of toothpaste contains 5 mg fluoride (as sodium fluoride), corresponding to 5000 ppm fluoride.

Excipient with known effect: 1 g of toothpaste contains 5 mg sodium benzoate.

This medicine contains 331.9 mg sorbitol in each 1 g of toothpaste which is equivalent to 33.19 % w/w (16.92 g per 51 g).

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Duraphat® 5000ppm Fluoride Toothpaste is a blue coloured toothpaste.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Prevention of dental caries in adolescents aged 16 years and over, and adults, particularly amongst patients at risk from multiple caries (coronal and/or root caries).

4.2. Posology and method of administration

Posology

Adult and adolescents aged 16 years and over

Brush carefully on a daily basis:

- apply a 2 cm ribbon onto your toothbrush for each brushing.
- 2 cm provides between 3 mg and 5 mg of fluoride.
- 3 times daily, after each meal.
- brush vertically, from the gum to the tip of the tooth.

Careful brushing takes approximately 3 minutes.

Not to be swallowed.

Paediatric population

For use by persons aged 16 years of age and over only (see section 4.4).

Method of administration

For dental use.

4.3. Contraindications

Duraphat® 5000ppm Fluoride Toothpaste must not be used in cases of hypersensitivity to the active substance or to any of the excipients.

4.4. Special warnings and precautions for use

Duraphat® 5000ppm Fluoride Toothpaste is not intended for use in adolescents and children under 16 years of age (see section 4.2). 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. Before using fluoride medicines such as Duraphat® 5000ppm Fluoride Toothpaste, an assessment of overall fluoride intake (i.e. drinking water, fluoridated salt, others fluoride medicines – tablets, drops, gum or toothpaste) should be done. Fluoride tablets, drops, chewing gum, gels or varnishes and fluoridated water or salt should be avoided during use of Duraphat® 5000ppm Fluoride Toothpaste. When carrying out overall calculations of the recommended fluoride ion intake, which is 0.05 mg/kg per day from all sources, not exceeding 1 mg per day, allowance must be made for possible ingestion of toothpaste (each tube of Duraphat 500 mg/100 g Toothpaste contains 255 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.

4.5. Interaction with other medicines and other forms of interaction

No known interactions have been established.

4.6. Fertility, pregnancy and lactation

Pregnancy

There is no adequate data from the use of Duraphat® 5000ppm Fluoride Toothpaste in pregnant women. Studies in animals have shown reproductive toxicity of sodium fluoride only when administered at very high levels. Therefore, this toothpaste should not be used during pregnancy.

Breast-feeding

There is no adequate data from the use of Duraphat® 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.

Fertility

No fertility data available

4.7. Effects on ability to drive and use machines

Duraphat® 5000 ppm Fluoride 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 to <1/1,000): Hypersensitivity reactions

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are requested to report any suspected adverse reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

4.9. Overdose

Acute intoxication: Fluoride

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. Where a substantial quantity of the medicinal product is ingested accidentally, 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.

Acute intoxication: Menthol

Duraphat® 5000ppm Fluoride Toothpaste contains menthol which if accidentally ingested at excessive amounts may cause convulsions, particularly in infants and children.

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

A.32.10 Dental Preparations

Pharmacotherapeutic group: Caries prophylactic agents ATC code: A01AA01. The primary mode of the caries preventative action of fluoride is post-eruptive, i.e. topical. Systemic fluoride supplements are believed to act also mainly topically (e.g. 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 inhibits the 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

Duraphat® 5000ppm Fluoride 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 swallowed during treatment. Any ingested fluoride is converted to hydrofluoric acid. Peak concentrations are reached within 30-60 minutes. The volume of distribution is 1l/kg. Fluoride ions are distributed to teeth and bones, and are not bound to plasma proteins. The terminal half-life is in the range two to nine 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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Liquid Sorbitol (Non-crystallising)

Dental Type Silica

Dental Type Silica (Precipitated)

Macrogol 600

Tetrapotassium Pyrophosphate

Xanthan Gum

Sodium Benzoate (E211)

Sodium Laurilsulfate

Spearmint flavouring (containing Peppermint Oil, Carvone, Spearmint Oil, Menthol, Anethol, and Lemon Oil)

Saccharin Sodium

Brilliant Blue FCF (E133)

Purified Water.

6.2 Incompatibilities

Not applicable

6.3 Shelf life

24 months

6.4 Special precautions for storage

Store at or below 25°C.

6.5 Nature and contents of container

51 g in a tube (PE/PET/aluminium) with a screw cap (polypropylene). The tube is packed inside an outer carton. Pack sizes: 1 x 51 g tube or 3 x 51 g tubes.

6.6 Special precautions for disposal

No special requirements

7 HOLDER OF CERTIFICATE OF REGISTRATION

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51/32.10/0102

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20 September 2022

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28 August 2025