Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Duraphat 5000 ppm Fluoride Toothpaste

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

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

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Toothpaste.

Product imported from Germany:
Blue paste.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

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

For use by persons aged 16 years of age and over only.

Not to be swallowed.

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.
- vertically, from the gum to the tip of the tooth.

Careful brushing takes approximately 3 minutes.

Method of administration: For dental use.

4.3 Contraindications

This medicinal product 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 500 mg/100 g Toothpaste is not intended for use in adolescents and children under 16 years of age, *see 4.2. Posology and method of administration.*

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, an assessment of overall fluor 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 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.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

There is no adequate data from the use of Duraphat 500 mg/100g 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 and lactation unless careful risk-benefit assessment has been carried out.

4.7 Effects on ability to drive and use machines

Not relevant.

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 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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: http://www.hpra.ie; E-mail:medsafety@hpra.ie.

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, 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 need to be kept under medical observation for several hours.

Acute intoxication: Menthol
Duraphat 500 mg/100 g 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

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 500 mg/100 g 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 1 L/kg. Fluoride ions are distributed to teeth and bones, and are not bound to plasma proteins. 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

Preclinical data reveal no special hazard for humans beyond the information included in other sections of the SPC.

After oral administration of sodium fluoride to mice, rats and rabbits reproductive and feto-toxic effects were observed only at high dose levels.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sorbitol solution 70% (non-crystallising)
Silica
Precipitated silica
Macrogol 600
Potassium diphosphate
Xanthan Gum
Sodium Benzoate
Sodium dodecyl sulfate

Spearmint flavour (containing Peppermint Oil, Carvone, Spearmint Oil, Levomenthol, Anethole and Lemon Oil)
Saccharin Sodium
Brilliant Blue FCF
Purified Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date of this product shall be the date shown on the container and outer package of the product o market in the country of origin.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

51g in a tube with a screw cap. The tube is packed inside an outer carton. Pack size: 1 x 51 g tube.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

LTT Pharma Limited
Unit 18, Oxleasow Road
East Moons Moat
Redditch
Worcestershire
B98 ORE
UK

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/123/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 15th August 2014

10 DATE OF REVISION OF THE TEXT