SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

DURAPHAT 2800 ppm FLUORIDE TOOTHPASTE

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Sodium Fluoride 0.619 % w/w (2800 ppm F)

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Toothpaste

Smooth White Paste

For dental use

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

For the prevention and treatment of dental caries (coronal and root) in adults and children over 10 years.

4.2 Posology and method of administration

Posology

Children under 10 years old: not recommended

Adults 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.

Elderly: use as for adults.

Method of administration
For dental use

4.3 Contraindications

Hypersensitivity to the active substance(s) or to any of the excipients

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.

4.5. Interactions with other medicinal products and other forms of interaction

None known.

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 newborn child.
No effects during pregnancy are anticipated, since systemic exposure to Sodium Fluoride is negligible. Duraphat 2800 Toothpaste can be used during pregnancy.
No effects on the breastfed newborn/infant are anticipated since the systemic exposure of the breast-feeding woman to Sodium Fluoride is negligible. Duraphat 2800 Toothpaste can be used during breast-feeding.

4.7. Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

When used as recommended there are no side effects.

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 Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

4.9 Overdose

Symptoms:
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.

Management:
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.

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% which corresponds to 280 mg fluoride per 100 g paste.

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

This product is not intended to be swallowed and therefore only minimal systemic exposure is expected.

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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol (E 422)
Purified Water
Sorbitol, liquid (non-crystallizing) (E 420)
Silicas
Polyethylene glycol 600
Sodium lauryl sulphate
Sodium carboxymethylcellulose (E 467)
Mint Flavour
Titanium dioxide (E 171)
Sodium saccharin (E954)

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

3 years

6.4. Special precautions for storage

Do not store above 25^{o}C.

6.5 Nature and contents of container

75 ml polyethylene/aluminium/polyethylene laminated tube with a polypropylene screw closure. Pack sizes: 1 x 75ml tube or 2 x 75ml tubes.

6.6 Special precautions for disposal and other handling

Not applicable

7. MARKETING AUTHORISATION HOLDER

Colgate-Palmolive (U.K.) Ltd
Guildford Business Park
Middleton Road
Guildford
Surrey GU2 8JZ
United Kingdom

8. MARKETING AUTHORISATION NUMBER

PL 00049/0039

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

4 December 2000

10 DATE OF REVISION OF THE TEXT

20/01/2015