

## Part II

### Summary of Product Characteristics

#### 1 NAME OF THE MEDICINAL PRODUCT

Duraphat 2800ppm Fluoride Toothpaste

#### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tube contains sodium fluoride 0.619 % w/w (2800 ppm fluoride).

For excipients, see 6.1.

#### 3 PHARMACEUTICAL FORM

Toothpaste  
Smooth white paste.

#### 4 CLINICAL PARTICULARS

##### 4.1 Therapeutic Indications

For the prevention and treatment of dental caries and demineralisation in adults and children over 16 years, who are at high risk of developing caries.

##### 4.2 Posology and method of administration

Adults and children over 16 years old: Use daily instead of the normal toothpaste. The usual dosage is to apply a line of paste (about 1g) 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 eat, drink or rinse for 30 minutes.

Children under 16 years: not recommended.

Elderly: use as for adults.

##### 4.3 Contraindications

None known.

Individuals with known hypersensitivity should consult their dentist before using.

Not to be used in children under 16 years old.

##### 4.4 Special warnings and precautions for use

Not to be swallowed.

##### 4.5 Interaction with other medicinal products and other forms of interaction

None known.

#### **4.6 Pregnancy and lactation**

Not applicable.

#### **4.7 Effects on ability to drive and use machines**

When used as recommended there are no side effects.

#### **4.8 Undesirable effects**

Not applicable.

#### **4.9 Overdose**

Not applicable.

### **5 PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic properties**

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.

#### **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**

The total amount of sodium fluoride in a 75 ml tube of Duraphat 2800 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**

Glycerol  
Purified water  
Sorbitol  
Hydrated silicas  
Macrogol 600  
Sodium laurilsulfate  
Carmellose sodium  
Flavour  
Titanium dioxide (E171)  
Saccharin sodium

#### **6.2 Incompatibilities**

Not applicable.

### **6.3 Shelf Life**

2 years.

### **6.4 Special precautions for storage**

Do not store above 25°C.

### **6.5 Nature and contents of container**

Aluminium tubes with an epoxy-phenolic lacquer coating which is resistant to acid and alkaline pH. The closure is a white polypropylene screw cap.

Tubes contain 15 ml, 50 ml or 75 ml of toothpaste.

### **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 MARKETING AUTHORISATION HOLDER**

Colgate-Palmolive (UK) Ltd  
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Middleton Road  
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## **8 MARKETING AUTHORISATION NUMBER**

PA 320/8/1

## **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 04 March 1999

Date of last renewal: 04 March 2004

## **10 DATE OF REVISION OF THE TEXT**

May 2004