

## Part II

### Summary of Product Characteristics

#### 1 NAME OF THE MEDICINAL PRODUCT

Fluorigard Gel-Kam

#### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Stannous Fluoride 0.4% w/w.

For excipients, see 6.1.

#### 3 PHARMACEUTICAL FORM

Oral gel

A gel for application to the teeth and gingivae of human beings.

#### 4 CLINICAL PARTICULARS

##### 4.1 Therapeutic Indications

As an aid in treatment and prevention of dental caries and decalcification of the teeth.

Fluorigard Gel-Kam gel will prevent caries, decalcification and demineralisation of the teeth when used on a daily basis.

Fluorigard Gel-Kam will also treat and arrest active surface caries in enamel and dentine preventing further carious breakdown of the dentition.

##### 4.2 Posology and method of administration

Recommended for adults and children over six years of age. The dosage for children, adults and the elderly is the same.

Apply Fluorigard Gel-Kam to a clean toothbrush, as you would a toothpaste, once a day at bedtime or as part of the last regular tooth brushing regime before retiring to bed. Brush Fluorigard Gel-Kam onto all the tooth surfaces; swish around for one minute, similar to a rinse, pushing the gel between the teeth with the tongue and cheek muscles, then spit out the excess. Do not swallow or rinse out.

Method of Administration: For dental use.

##### 4.3 Contraindications

Hypersensitivity to one or more of the ingredients.

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

Do not use more than the recommended dose.

Do not swallow the excess gel.

**Do not use on children under six years.**

Keep out of the reach of children.

Close bottle after use.

Health professionals should be aware of the total daily use of fluoride from all sources.

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

Stannous Fluoride may potentiate the efficacy of sodium fluoride and acidulated phosphate preparations in reducing enamel solubility.

No known interactions with food and alcohol.

## 4.6 Pregnancy and lactation

Fluorigard Gel-Kam can be used during pregnancy and lactation.

## 4.7 Effects on ability to drive and use machines

None.

## 4.8 Undesirable effects

Fluorigard Gel-Kam will not stain intact enamel but there may be superficial light brown pigmentation of plaque if the teeth are not cleaned properly. This is easily removed by professional scaling and prophylaxis. It may be minimised by the use of a conventional toothpaste prior to using Fluorigard Gel-Kam.

## 4.9 Overdose

None reported.

Symptoms in acute fluoride poisoning are gastralgia, nausea, vomiting, tetany, muscle weakening (twitching often occurs) collapse.

Emergency treatment consists of:

- i Emesis and gastric lavage.
- ii Give milk for its calcium content and for its demulcent action. Lime water may also be used.
- iii Soluble calcium salts are given intravenously.
- iv Procainamide hydrochloride 0.5 to 1.0g orally or half of this amount intravenously every 4 to 6 hours until the patient improves.

# 5 PHARMACOLOGICAL PROPERTIES

## 5.1 Pharmacodynamic properties

0.4% Stannous Fluoride prevents and treats dental caries and decalcification by increasing the resistance of the enamel and root surfaces of the teeth to acid attack. Of the fluorides available for topical application, stannous fluoride has proved to be the fluoride of choice due to the fact that the stannous ion combines with the naturally occurring phosphate in the enamel to form stannous fluorophosphate which serves as a protective coating to the tooth.

## 5.2 Pharmacokinetic properties

0.4% Stannous Fluoride should be used daily for the most efficacious results. Studies have shown that if it is not used daily then the incidence of caries may increase. When used daily, 0.169 mg of fluoride ion may be ingested when the excess is expectorated. Should the total dosage on a standard toothbrush be swallowed then 1.08 mg of fluoride may be ingested. Practitioners should be aware of the total daily dose of fluoride ion from all sources including toothpaste.

### 5.3 Preclinical safety data

Fluorides have been in widespread use in dental practice for many years. Safety in man is well documented therefore no statements on Preclinical Safety are made.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Glycerol  
Hydroxyethylcellulose  
Crème de menthe/ Mint flavour F-1328

### 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

White LDPE bottle fitted with a flip-top and child resistant polyethylene closure.  
Pack sizes: 50ml and 100ml.

### 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) Limited  
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## 8 MARKETING AUTHORISATION NUMBER

PA 320/4/1

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

Date of first authorisation: 03 April 1998

Date of last renewal: 03 April 2003

**10 DATE OF REVISION OF THE TEXT**

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