

## Part II

### Summary of Product Characteristics

#### 1 NAME OF THE MEDICINAL PRODUCT

PEROXYL 1.5% Mouthwash

#### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Hydrogen peroxide 1.5% w/v.

For excipients, see 6.1.

#### 3 PHARMACEUTICAL FORM

Mouthwash

A clear aqua – blue liquid.

#### 4 CLINICAL PARTICULARS

##### 4.1 Therapeutic Indications

As a cleanser in the symptomatic relief of minor mouth and gum irritations.

##### 4.2 Posology and method of administration

Oromucosal use.

Peroxyl is ready to use. Rinse with 10 ml (half a capful) for approximately one minute, then spit out. Use 3 times daily (after meals and at bedtime) or as directed by a doctor or dentist.

Adults and children over 12 years: as above.

Children between 6-12 years old: Use under the supervision of an adult.

The duration of treatment should not exceed 7 days.

##### 4.3 Contraindications

Hypersensitivity to the active ingredient or other compounds in the preparation. Do not use in children under the age of 6.

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

Do not swallow.

If irritation persists for 7 days, is severe, is due to orthodontic appliances and/or dentures, or swelling or fever develops the patient's condition needs to be re-evaluated.

Overdose can injure the gums and continued use of hydrogen peroxide may cause reversible hypertrophy of the papillae of the tongue known as “black hairy tongue” therefore using this product at high doses or for long periods of time is not recommended.

Avoid contact with eyes.

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

Not applicable.

## 4.6 Pregnancy and lactation

Although there are not sufficient specific clinical data on the use of Peroxyl in this patient group, self-administration without medical advice is not recommended.

## 4.7 Effects on ability to drive and use machines

Not applicable.

## 4.8 Undesirable effects

Some cases of mucosal irritation and swelling of the oral tissues have been reported specially with high doses or in continued use (see special warnings, above). The symptoms will resolve on stopping treatment with Peroxyl.

## 4.9 Overdose

Peroxyl is a dilute hydrogen peroxide solution and is unlikely to cause the symptoms of overdose associated with strong solutions (30-40%).

# 5 PHARMACOLOGICAL PROPERTIES

## 5.1 Pharmacodynamic properties

Hydrogen peroxide is an oral antiseptic cleanser. The principal action is brought about by contact of hydrogen peroxide with peroxidases and catalases present in tissues and saliva, which causes the rapid release of oxygen. This provides mechanical cleansing which flushes out mouth debris, and helps in the treatment of oral irritations.

## 5.2 Pharmacokinetic properties

In the mouth, salivary peroxidase breaks down hydrogen peroxide to release water and oxygen.

## 5.3 Preclinical safety data

Low doses of hydrogen peroxide do not produce tissue damage or result in neoplastic changes. Application of Peroxyl to abraded mucosa in the hamster cheek pouch study over 21 days showed no adverse effect.

Hydrogen peroxide is not genotoxic in animals. The available data on reproduction toxicology are incomplete but do not indicate an effect at low concentrations.

# 6 PHARMACEUTICAL PARTICULARS

## 6.1 List of excipients

Purified water  
Sorbitol (non-crystallising) 70% w/w (E420)  
Ethanol 96%  
Poloxamer 338  
Polysorbate 20  
Methyl salicylate  
Levomenthol

Sodium saccharin  
Brilliant blue (E133)

## 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

The solution is packaged in polyethylene terephthalate (PETE) bottles with a polypropylene dosage cap, capacity 250 ml, 300 ml or 473 ml.

Not all pack sizes may be marketed.

## 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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## 8 MARKETING AUTHORISATION NUMBER

PA 320/6/1

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

Date of first authorisation: 03 March 2000

Date of last renewal: 03 March 2005

## 10 DATE OF REVISION OF THE TEXT

November 2005