

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Peroxyl TM Mouthwash.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

100ml of solution contains 1.5g of Hydrogen peroxide (as 30% Hydrogen Peroxide solution).

For a full list of excipients, see section 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

Do not use in children under the age of 6.

Peroxyl is ready to use. Rinse with 10 ml (one capful, 10 ml line within cap) 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 the treatment should not exceed 7 days.

Method of administration: Oromucosal use.

4.3. Contraindications

This medicinal product must not be used in cases of hypersensitivity of the active substance or to any of the excipients.

4.4. Special warning 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 by a doctor or dentist.

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

None known

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 relevant

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.

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

4.9. Overdose

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

Peroxyl contains levo-menthol which if accidentally ingested at excessive amounts may cause convulsions, particularly in infants and children.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: Antiinfectives and antiseptics for local oral treatment

ATC code: A01AB02

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. Pre-clinical 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 reproductive toxicology are incomplete but do not indicate an effect at low concentrations.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Purified Water
Sorbitol 70% w/w (non-crystallising)
Ethanol 96%
Poloxamer 388
Polysorbate 20
Methyl salicylate
Levo-Menthol
Sodium saccharin
Brilliant Blue FCF (E133)

6.2. Incompatibilities

Not applicable.

6.3 Shelf life

24 months (300 ml pack size)

6.4. Special Precautions for Storage

Do not store above 25°C.

6.5 Nature and contents of container

300 ml in bottle (PET), with polyethylene cap

6.6. Special precautions for disposal

No special requirements

7. MARKETING AUTHORISATION HOLDER

Colgate-Palmolive (UK) Ltd
Guildford Business Park
Middleton Road
Guildford
Surrey GU2 8JZ
UK

8. MARKETING AUTHORISATION NUMBER(S)

PL 00049/0038

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

29/11/2006

10 DATE OF REVISION OF THE TEXT

17/02/2016