

EFFECTIVE TREATMENT & PREVENTION FOR ORAL HYGIENE

Chlorhexidine Gluconate Mouthwash

0.2% w/v Chlorhexidine Gluconate Oromucosal Solution

Antiseptic Mouthwash

Chlorhexidine Gluconate Mouthwash is firmly established as the mouthwash of clinical choice. It is the proven, prescribed and recommended treatment for gingivitis and oral hygiene.

- ▲ High quality Chlorhexidine Gluconate mouthwash
- ▲ Formulation of choice for dentists and doctors
- ▲ Two pleasant tasting flavours
- ▲ Licensed by the Medicines and Healthcare products Regulatory Agency (MHRA) in the UK and Health Products Regulatory Authority (HPRA) in Ireland, providing guaranteed safety and efficacy



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0.2% w/v Chlorhexidine Gluconate Oromucosal Solution

Antiseptic Mouthwash

Why Use Chlorhexidine Gluconate Mouthwash?

IDEAL FOR IMMUNOCOMPROMISED PATIENTS

Highly effective 0.2% Chlorhexidine Gluconate mouthwash.

- Effective in reducing plaque accumulation when used twice a day
- Can be effectively used to manage gingivitis
- For immunocompromised patients it is the ideal product for oral hygiene
- Can be used to help promote healing after periodontal treatment

BROAD SPECTRUM EFFICACY

The active chlorhexidine gluconate, a broad spectrum antiseptic, is effective against a wide range of both Gram positive and Gram negative bacteria, yeast, fungi and viruses¹.

LICENSED ANTISEPTIC MOUTHWASH

Licensed Antiseptic Mouthwash
Chlorhexidine Gluconate Mouthwash has been granted a marketing authorisation by the Medicines and Healthcare products Regulatory Agency (MHRA) in the UK and Health Products Regulatory Authority (HPRA) in Ireland, providing assurance that the product's safety and efficacy has been assessed before marketing.



Chlorhexidine
Gluconate Mouthwash
Original Flavour



Chlorhexidine
Gluconate Mouthwash
Peppermint Flavour

SUMMARY OF PRODUCT CHARACTERISTICS

Chlorhexidine Gluconate Mouthwash - Original Flavour
Chlorhexidine Gluconate Mouthwash - Peppermint Flavour

Name of Medicinal Product: Chlorhexidine Gluconate Antiseptic Mouthwash 0.2% w/v oromucosal solution, active ingredient chlorhexidine gluconate 0.2% w/v. **Indications:** Chlorhexidine Gluconate Antiseptic Mouthwash is an antimicrobial solution which inhibits the formation of dental plaque. It is indicated as an aid to the treatment and prevention of gingivitis and in the maintenance of oral hygiene, particularly in situations where tooth brushing cannot be adequately employed (e.g. following oral surgery or in physically handicapped patients). It is used to promote gingival healing following periodontal surgery, to manage recurrent oral ulceration. Additionally it is useful in the treatment of denture stomatitis and thrush. **Undesirable effects:** **Immune disorders;** Frequency: not known - hypersensitivity including anaphylactic shock. **Skin disorders;** Frequency: not known - allergic skin reactions such as dermatitis, pruritus, erythema, eczema, rash, urticarial, skin irritation, and blisters, following topical application. Chemical burns in neonates and infants, following topical application. **Gastrointestinal disorders;** Frequency: uncommon - a superficial discolouration of the dorsum of the tongue may occur. This disappears after treatment is discontinued. Discolouration of the teeth and silicate or composite restorations may also occur. This stain is not permanent and can largely be prevented by brushing with a conventional toothpaste daily before using the mouthwash. However, in certain cases, a professional prophylaxis (scaling and polishing) may be required to remove this stain completely. Stained anterior tooth-coloured restorations with poor margins or rough surfaces which are not adequately cleaned by professional prophylaxis may require replacement. Similarly where normal tooth brushing is not possible, as for example with intermaxillary fixation or with extensive orthodontic appliances, scaling and polishing may also be required once the underlying conditions have been resolved. **Very rare** - In cases where oral desquamation occurs it may be necessary to discontinue treatment. Very occasionally, swelling of the parotid glands during the use of oral chlorhexidine has been reported. In all cases spontaneous resolution has occurred on discontinuing treatment. **Nervous System disorders;** Frequency: Common - Transient disturbances of taste sensation and a burning sensation of the tongue may occur on initial use of the mouthwash. These effects usually diminish with continued use. **Contraindications:** Known hypersensitivity to the product or any of its components, especially in those with a history of possible chlorhexidine-related allergic reactions. **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, Website: www.mhra.gov.uk/yellowcard. Healthcare professionals in the Republic of Ireland are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. **Warnings:** Chlorhexidine Gluconate Antiseptic Mouthwash contains chlorhexidine. Chlorhexidine is known to induce hypersensitivity, including generalised allergic reactions and anaphylactic shock. The prevalence of chlorhexidine hypersensitivity is not known, but available literature suggests this is likely to be very rare. Chlorhexidine Gluconate Antiseptic Mouthwash should not be administered to anyone with a potential history of an allergic reaction to a chlorhexidine-containing compound. For oral use only. Keep away from the eyes and ears. If solution comes into contact with the eyes, wash out well with water. Keep out of the reach and sight of children. Ponceau 4R may cause allergic reactions. Macrogol glycerol hydroxystearate may cause skin reactions. **Pregnancy and lactation:** Chlorhexidine has been in widespread use for many years and no harmful effects in human pregnancy have been reported. However as with all drugs, caution should be exercised. Chlorhexidine Gluconate Antiseptic Mouthwash should be used only when the benefit to the mother has been assessed by a clinician. **Posology and method of administration:** Children, adults and the elderly. Chlorhexidine Gluconate Antiseptic Mouthwash should be used as required up to twice daily. Rinse the mouth thoroughly for about 1 minute with 10 ml. Prior to dental surgery, the patient should be instructed to rinse the mouth with 10 ml for 1 minute. In the treatment of gingivitis a course of about one month is recommended (i.e. two bottles). For denture stomatitis cleanse and soak the denture in solution for 15 minutes twice daily. In the case of aphthous ulceration and oral candidal infections, treatment should be continued for 48 hours after clinical resolution. **Marketing Authorisation Holder:** Ecolab Ltd, Lotherton Way, Garforth, Leeds, LS25 2JY. **Marketing Authorisation number:** Original: PL 04509/0009 PA 1110/11/1, Peppermint: PL 04509/0010 PA 1110/11/2. **Sales Status:** GSL. Please read carefully the instructions on the SPC and on the label leaflet. **Date of Revision of the Text:** July 2015/October 2015.

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TRUSTED.
RELIABLE.
EFFECTIVE.

INDICATIONS FOR USE

Chlorhexidine Gluconate Mouthwash is suitable for:

- Reducing plaque accumulation
- Managing gingivitis
- Promoting healing after periodontal treatment
- General oral hygiene

INGREDIENTS

Chlorhexidine Gluconate Mouthwash - An Oromucosal Solution containing Chlorhexidine Gluconate 0.2% w/v.

PACKAGING AND ORDERING INFORMATION

PRODUCT	OUTER SIZE	ECOLAB Order Code	NHSCC Order Code
Chlorhexidine Gluconate Mouthwash Original Flavour Bottle	12 x 300ml	3037080	MRB297
Chlorhexidine Gluconate Mouthwash Peppermint Flavour Bottle	12 x 300ml	3037100	MRB296

REFERENCE

- Denton, GW; "Chlorhexidine." Chapter 15 in Disinfection, Sterilization and Preservation. Ed. Block SS. Fifth Ed. Lippincott Williams and Wilkins, 2001.