Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Chlorhexidine Gluconate Antiseptic Mouthwash Original Flavour 0.2% w/v Oromucosal Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Chlorhexidine Gluconate 0.2% w/v

Excipients with known effect: Ponceau 4R 0.001%w/w
Macrogol glycerol hydroxystearate 0.7 % w/w

For full list of excipients see Section 6.1

3 PHARMACEUTICAL FORM

Oromucosal Solution.

A clear pink solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic 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 toothbrushing cannot be adequately employed (eg 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.

4.2 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 (ie 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.

4.3 Contraindications

Known hypersensitivity to the product or any of its components, especially in those with a history of possible chlorhexidine-related allergic reactions (see sections 4.4 and 4.8).

4.4 Special warnings and precautions for use

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 (see sections 4.3 and 4.8).

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.

4.5 Interaction with other medicinal products and other forms of interaction

Chlorhexidine Gluconate 0.2% is incompatible with anionic agents which are usually present in conventional dentifrices. These should therefore be used before Chlorhexidine Gluconate Antiseptic Mouthwash (rinsing the mouth between applications) or at a different time of the day.

4.6 Fertility, 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.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Immune disorders
Frequency not known: hypersensitivity including anaphylactic shock (see sections 4.3 and 4.4)

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
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 toothbrushing 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:
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.

System Organ Class	**Very Common (≥ 1/10)**	**Common (≥ 1/100 < 1/10)**	**Uncommon (≥ 1/1,000 < 1/100)**	**Rare (≥1/10,000 < 1/1,000)**	**Very Rare (< 1/10,000)**	**Not known (cannot be estimated from available data)**

Gastrointestinal Disorders			**Tooth discolouration** **Tongue discolouration**		**Oral mucosal exfoliation (desquamation)** **Parotid gland enlargement**	
Immune System Disorders						**Hypersensitivity** **Anaphylactic shock**
Nervous System Disorder		**Dysgeusia (taste altered)**				
Skin and Subcutaneous Tissue Disorders						**Allergic skin reactions Chemical Burns (Neonates and infants)**

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

Chlorhexidine is poorly absorbed by the oral route, therefore systematic effects are unlikely even if large volumes are swallowed. However, gastric lavage followed by supportive measures may be used as appropriate.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Chlorhexidine gluconate is a bisguanide antiseptic and disinfectant which is bactericidal or bacteriostatic against a wide range of gram negative and gram positive vegetative bacteria, yeasts, dermatophyte fungi and lipophylic viruses. The antimicrobial activity covers most of the important species occuring in the oral microflora.

5.2 Pharmacokinetic properties

Because of its cationic nature, chlorhexidine (gluconate) binds strongly to skin, mucosa and other tissues and is thus very poorly absorbed. No detectable blood levels have been found following oral use.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Chlorhexidine Gluconate Antiseptic Mouthwash contains the following inactive ingredients:
Ethanol
Sorbitol
Macrogol glycerol hydroxystearate
Original Flavour: E2309 10 N1
Ponceau 4R
Purified Water

6.2 Incompatibilities

Chlorhexidine Gluconate Antiseptic Mouthwash is incompatible with anionic agents which are often present in toothpastes. Therefore these should be used before the mouthwash, rinsing the mouth between applications, or at a different time of day.

Hypochlorite bleaches may cause brown stains to develop in fabrics previously in contact with chlorhexidine.

6.3 Shelf life

Two years.

6.4 Special precautions for storage

Do not store above 25°C.
Store in the original container in order to protect from light.

6.5 Nature and contents of container

Amber PET bottle with a polypropylene screw cap. The cap is conical in shape and has "10 ml" and a level line engraved on the inside. The pack contains 300 ml.

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

Ecolab Deutschland GmbH
Ecolab-Allee 1
D-40789 Monheim am Rhein
Germany

8 MARKETING AUTHORISATION NUMBER

PA1843/003/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 18 February 2000
Date of last renewal: 12 March 2008

10 DATE OF REVISION OF THE TEXT

March 2023