SUMMARY OF PRODUCT CHARACTERISTICS

1.7 PRODUCT INFORMATION

1.7.1 SUMMARY OF PRODUCTCHARACTERISTICS

1. Name of the medicinal product

1.1 (Invented) name of the medicinal product :

- **Generic Name/Inn Name:**
  Chlorhexidine Mouthwash

- **Brand Name:**
  AWE MOUTHWASH

1.2 Strength :
Chlorhexidine Gluconate Solution BP dilute to Chlorhexidine Gluconate 0.2%

1.3 Pharmaceutical form :
Oral Mouthwash

2. Qualitative and quantitative composition
Composition:

Chlorhexidine Gluconate Solution BP dilute to Chlorhexidine Gluconate 0.2% w/v
For a full list of excipients, see section 6.1.

3. Pharmaceutical form:

Dosage Form: Oral Mouthwash

- **Visual & Physical characteristics of the product:** Blue colored clear 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 tooth brushing 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

4.4 Special warnings and precautions for use:

Chlorhexidine Gluconate Antiseptic Mouthwash contains chlorhexidine. Chlorhexidine is known to induce hypersensitivity, including generalized 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. 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 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 stated.

4.8 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
Uncommon:
- A superficial discoloration of the dorsum of the tongue may occur. This disappears after treatment is discontinued. Discoloration 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:
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						Hypersensitivity Anaphylactic shock

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:

Glycerin, Sorbitol solution 70 % , Propylene glycol,Menthol,Cresmer RH 40 , Colour Brilliant Blue & Peppermint C7531 .

6.2 Incompatibilities:

None Known

6.3 Shelf life:

36 Months

6.4 Special precautions for storage:

Store in a dark place at temperature not exceeding 30 °C.

6.5 Nature and contents of container:

100 ml transparent PET round bottle with Measuring cup, Label and leaflet in one monocarton.

6.6 Special precautions for disposal:

No special instructions needed

7 . Registrant:

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9. Date of revision of the text
