Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Corsodyl 0.2% w/v Aniseed Mouthwash

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Chlorhexidine Digluconate 0.2% w/v
(as Chlorhexidine Digluconate Solution).

Excipients: Contains Macrogolglycerol Hydroxystearate 0.8% w/v
For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Mouthwash.

A clear to slightly opalescent, transparent solution with an odour of aniseed.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the inhibition of the formation of dental plaque.
As an aid in 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 or mentally handicapped patients).
Also for use in a post-periodontal surgery or treatment regimen to promote gingival healing.
It is useful in the management of aphthous ulceration and oral candidal infections (e.g. denture stomatitis and thrush).

4.2 Posology and method of administration

Adults:

Thoroughly rinse the mouth for about one minute with 10 ml twice daily. Spit out after use. In the dental surgery the patient should be instructed to rinse the mouth with 10 ml for one minute prior to treatment.

For the treatment of gingivitis, a course of about one month is advisable although some variation in response is to be expected. In the case of aphthous ulceration and oral candidal infections, treatment should be continued for 48 hours after clinical resolution. For the treatment of denture stomatitis the dentures should be cleansed and soaked in Corsodyl Mouthwash for fifteen minutes twice daily.

Do not exceed the stated dose.

Children and the Elderly:

There are no special dosage recommendations for either elderly patients or children of 12 years and over. The normal adult dose is appropriate unless otherwise recommended by the dentist or the physician.

Children under 12 years of age should not use the product unless recommended by a healthcare professional.

4.3 Contraindications

Hypersensitivity to chlorhexidine digluconate or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

For oral (external) use only. Do not swallow.

Keep out of the eyes and ears.

If the mouthwash comes into contact with the eyes, wash out promptly and thoroughly with water.

In case of soreness, swelling or irritation of the mouth, stop using the product and consult a healthcare professional.

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

In case of swelling or difficulty breathing, stop using the product and seek immediate medical help. Transient disturbances of taste sensation and a numbness, tingling or burning sensation of the tongue may occur on initial use of the mouthwash. These effects usually diminish with continued use. If the condition persists, consult a healthcare professional.

Discoloration of the teeth and tongue may occur. The stain is not permanent and can largely be prevented by reducing the consumption of dietary chromagens such as tea, coffee or red wine. In the case of dentures this can be prevented by cleaning with a conventional denture cleaner. In certain cases professional treatment (scaling and polishing) may be required to remove the stain completely.

Macrogoglycerol hydroxystearate may cause skin reactions.

4.5 Interaction with other medicinal products and other forms of interaction

Chlorhexidine is incompatible with anionic agents.

4.6 Fertility, pregnancy and lactation

There is no evidence of any adverse events on the foetus arising from the use of Corsodyl Aniseed Mouthwash during pregnancy or lactation. Therefore, no special precautions are recommended.

4.7 Effects on ability to drive and use machines

None have been reported or are known.

4.8 Undesirable effects

Adverse events are listed below by system organ class and frequency. Frequencies are defined as: Very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1000 to <1/100); rare (≥1/10,000 to <1/1000); and very rare (<1/10,000). The data from clinical trials are estimates. Post-marketing data refer to reporting rate rather than true frequency.

Clinical Trial Data

Gastrointestinal Disorders
Very Common: Tongue coated

Common: Dry mouth

Nervous system disorders
Common: Aguesia / dysguesia
Glossodynia
Oral paraesthesia / hypoaesthesia

Post Marketing Data

Gastrointestinal Disorders
Isolated Reports: Discoloration of the teeth and tongue (see Warnings and Precautions)
Irritation of the mouth (see Warnings and Precautions)
Desquamation / swelling of oral mucosa (see Warnings and Precautions)
Parotid gland swelling

Immune System Disorders
Isolated Reports: Hypersensitivity and anaphylaxis (see Contraindications, Warnings and Precautions)

Undesirable effects are generally minor and local in nature.

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. Website: http://www.hpra.ie

4.9 Overdose

Accidental Ingestion
Chlorhexidine taken orally is poorly absorbed. Systemic effects are unlikely even if large volumes are ingested. However, gastric lavage may be advisable using milk, raw egg, gelatin or mild soap. Employ supportive measures as appropriate. Due to the alcohol content (7 % v/v), ingestion of large amounts by children requires attention, seek medical advice for appropriate action.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Corsodyl Mouthwash contains 0.2% w/v chlorhexidine digluconate which is an antimicrobial preparation for external use. It is effective against a wide range of gram negative and gram positive vegetative bacteria, yeasts, dermatophyte fungi and lipophilic viruses. It is active against a wide range of important oral pathogens and is therefore effective in the treatment of many common dental conditions.

5.2 Pharmacokinetic properties

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

5.3 Preclinical safety data

Pre-clinical safety studies carried out on chlorhexidine digluconate have not revealed any pertinent findings which are of relevance to the recommended dosage and use of the product and which have not already been mentioned elsewhere in the Summary.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol,
Macrogolglycerol Hydroxystearate,
Sorbitol Liquid 70% (non crystallising),
Aniseed Flavour (Optamint Lighthouse 911218),
Purified Water.

6.2 Incompatibilities

Chlorhexidine is incompatible with anionic agents. Hypochlorite bleaches may cause brown stains to develop in fabrics which have previously been in contact with preparations containing chlorhexidine.

6.3 Shelf life

Three years.

6.4 Special precautions for storage

Do not store above 25°C. Use within 6 months of opening. Store in the original container in order to protect from light.

6.5 Nature and contents of container

Amber-coloured, biaxially-oriented, polyethylene terephthalate (PET) bottles of nominal capacity of 300 ml fitted with white polypropylene screw caps.

Or

Amber-coloured, biaxially-oriented, recycled polyethylene terephthalate (rPET) bottles of nominal capacity of 300 ml fitted with white polypropylene screw caps.

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

Haleon Ireland Limited
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8 MARKETING AUTHORISATION NUMBER

PA0678/002/004

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 10 January 1995

Date of last renewal: 10 January 2010

10 DATE OF REVISION OF THE TEXT

August 2026