

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Corsodyl 1% w/w Dental Gel

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Chlorhexidine digluconate 1% w/w (as Chlorhexidine digluconate Solution).

Excipients: Contains Macrogolglycerol Hydroxystearate 1% w/w

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Dental Gel

A clear or faintly opalescent, transparent, colourless or slightly coloured gel with an odour of peppermint.

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.

As an aid to maintaining oral hygiene.

For use in a post-periodontal surgery or treatment regimen to promote gingival healing.

It is useful in the management of recurrent aphthous ulceration.

It is useful in the management of recurrent oral candidal infections.

It may also be used as part of a preventative programme to help reduce caries activity.

4.2 Posology and method of administration

Adults:

Brush the teeth thoroughly with one inch of gel on a moistened toothbrush, once or twice daily for about one minute. Spit out any excess. Do not rinse after applying gel.

For the treatment of gingivitis, a course of about one month is advisable.

When used for the management of aphthous ulceration and oral candidal infections an alternative method of delivery may be required which facilitates application of the gel to the affected areas. This should be used once or twice daily for about one minute. The length of treatment time should be decided on the basis of clinical response.

During the treatment of denture stomatitis thoroughly brush all over the dentures with 2.5 cm of gel on a moistened toothbrush, once or twice daily for about one minute.

For the prevention of caries, 1-2 inches of 'Corsodyl' Dental Gel should be applied to the teeth daily, preferably by close-fitting tray, remaining in contact with the teeth for 5 minutes. The treatment should be continued for up to 14 days. At the same time the patient should be encouraged to undertake adjunctive preventive measures, such as reducing the frequency of intake of

refined carbohydrates and brushing the teeth twice daily with a fluoride-containing dentifrice. Additionally professional fluoride applications and fissure sealing may be useful as part of the preventative programme.

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 gel 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 Dental Gel is incompatible with anionic agents which are usually present in conventional dentifrices. These should therefore be used before Corsodyl (rinsing the mouth and toothbrush 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 gel. 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.

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 effects on the foetus arising from the use of Corsodyl Dental Gel 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 ($\geq 1/10$); common ($\geq 1/100$ to $< 1/10$); uncommon ($\geq 1/1000$ to $< 1/100$); rare ($\geq 1/10,000$ 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 HPRC Pharmacovigilance, website: 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.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Corsodyl 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

Hydroxypropylcellulose
Macrogolglycerol Hydroxystearate
Sodium Acetate
Levomenthol
Peppermint Oil
Isopropyl Alcohol
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. Use within one month of opening.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Container

Collapsible internally-lacquered aluminium tubes.

Closure

White, food grade HDPE cap. Wadless with plug seal.

Pack size

50g.

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
12 Riverwalk
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Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0678/002/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 29 April 1975

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10 DATE OF REVISION OF THE TEXT

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Page 4 of 4