

Corsodyl Original Mouthwash

Summary of Product Characteristics Updated 24-Jun-2020 | GlaxoSmithKline Consumer Healthcare

1. Name of the medicinal product

Corsodyl Original Mouthwash

Corsodyl Mouthwash Original

2. Qualitative and quantitative composition

Chlorhexidine Digluconate 0.2% w/v

(equivalent to Chlorhexidine Digluconate Solution Ph. Eur. 1.0% v/v)

3. Pharmaceutical form

Oromucosal solution

4. Clinical particulars

4.1 Therapeutic indications

Corsodyl Mouthwash is an antimicrobial solution which inhibits the formation of dental plaque.

It is indicated 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, in mentally or physically handicapped patients).

Also for use in a post-periodontal surgery or treatment* regimen to promote gingival healing.

*NB: Use as part of a post-periodontal treatment regimen has only been adequately studied over the short term and following standard root surface instrumentation.

It is useful in the management of aphthous ulceration and oral candidal infections (eg 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 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 dental 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:

The normal adult dose is appropriate for elderly patients and children of 12 years and over 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.

Route of administration

External (oral) use. [This product is not intended to be swallowed].

4.3 Contraindications

Corsodyl is contraindicated for patients who have previously shown a hypersensitivity reaction to Chlorhexidine or to any of the excipients in the formulation.

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 is incompatible with anionic agents which are usually present in conventional dentifrices. These should therefore be used before Corsodyl (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. 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, for example with intermaxillary fixation, or with extensive orthodontic appliances, scaling and polishing may also be required once the underlying condition has been resolved.

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 during pregnancy or on infants during 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 section 4.4)

Irritation of the mouth (see section 4.4)

Desquamation / swelling of oral mucosa (see section 4.4)

Parotid gland swelling

Immune System Disorders

Isolated reports: Hypersensitivity and anaphylaxis (see section 4.3 and 4.4)

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Due to the alcohol content (7.0 % v/v) ingestion of large amounts by children requires attention. Seek medical advice for appropriate action.

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

Chlorhexidine 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

No information further to that contained in other sections of the SPC is included.

6. Pharmaceutical particulars

6.1 List of excipients

Ethanol (96 per cent),
Macrogolglycerol Hydroxystearate,
Ponceau 4R (E124),
Aniseed Flavouring Oil,
Peppermint oil,
Purified water.

6.2 Incompatibilities

Hypochlorite bleaches may cause brown stains to develop in fabrics that have previously been in contact with preparations containing chlorhexidine.

6.3 Shelf life

Three years.

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

Oriented amber polyethylene terephthalate bottle with plastic screw cap made from white food grade polypropylene.
Each bottle contains 300 ml or 600 ml.

6.6 Special precautions for disposal and other handling

None.

7. Marketing authorisation holder

GlaxoSmithKline Consumer Healthcare (UK) Trading Limited
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8. Marketing authorisation number(s)

PL 44673/0061

9. Date of first authorisation/renewal of the authorisation

10 February 1994 / 09 September 2008

10. Date of revision of the text

17/6/20.

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