

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Corsodyl 0.2% Mouthwash

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Chlorhexidine Digluconate 0.2% w/v
(equivalent to Chlorhexidine Digluconate Solution 1.028% w/w)

Also contains macrogolglycerol hydroxystearate. For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oromucosal solution

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

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Antibacterial solution for the disinfection of the mouth.

1. As an aid to maintaining oral hygiene.
2. As an aid in the treatment and prevention of gingivitis.
3. Inhibition of formation of dental plaque.
4. For use in aphtous ulceration and oral candidal infections (eg denture stomatitis and thrush).
5. For use in a post- periodontal surgery or treatment regimen to promote gingival healing.

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 0.2% 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

Oromucosal use. [This product is not intended to be swallowed].

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

For oromucosal 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 0.2% Mouthwash is incompatible with anionic agents which are usually present in conventional dentifrices. These should therefore be used before Corsodyl 0.2% 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. 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.

Macrogolglycerol 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 effects on the foetus arising from the use of chlorhexidine digluconate 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 suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form

<https://sideeffects.health.gov.il/>

Additionally, please also report to GSK Israel (il.safety@gsk.com)

4.9 Overdose

This has not been reported.

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

Pharmacotherapeutic group: anti-infectives and antiseptics for local oral treatment

ATC code: A01AB03

Corsodyl 0.2% 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

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

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Purified water
Sorbitol
Glycerol
Macrogolglycerol Hydroxystearate
Peppermint flavour

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

The expiry date of the product is indicated on the packaging materials.

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

Oriented amber polyethylene terephthalate (PET) bottle with plastic screw cap made from white food grade polypropylene.

Each bottle contains 300 ml.

6.6 Special precautions for disposal and other handling

None.

7 MANUFACTURER

Purna Pharmaceuticals,
Rijksweg 17
2870 Puurs
Belgium

8. MARKETING AUTHORISATION HOLDER

GSK Consumer Healthcare Israel Ltd.
P.O.Box 3256
Petach - Tikvah
Israel

9. MARKETING AUTHORISATION NUMBER(S)

029-96-21599-00

The content of this leaflet was revised in January 2021.