This leaflet format has been determined by the Ministry of Health and the content has been checked and approved in January 2019

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Chlorhexidine Lacer Mouthwash

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Chlorhexidine Digluconate 0.12% w/v

(equivalent to Chlorhexidine Digluconate Solution 0.636% w/w)

Also contains PEG-40 Hydrogenated Castor Oil. For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oromucosal solution

Colourless solution and with a characteristic odour.

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 (e.g. 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 15 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 Chlorhexidine Lacer 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

Chlorhexidine Lacer Mouthwash is contraindicated for patients who have previously shown a hypersensitivity reaction to Chlorhexidine or to any of the excipients in the formulation (listed in secion 6.1). However, such reactions are extremely rare.

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.

Chlorhexidine Lacer Mouthwash is incompatible with anionic agents which are usually present in conventional dentifrices. These should therefore be used before Chlorhexidine Lacer 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.

PEG-40 Hydrogenated Castor Oil 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 (≥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 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 authorization 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://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il

4.9 Overdose

Overdose 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

Chlorhexidine Lacer Mouthwash contains 0.12% 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 SmPC is included.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water
Propylene Glycol
Glycerin
Xylitol
PEG-40 Hydrogenated Castor Oil
Poloxamer 407
Aroma (Limonene, E-Anethole, L-Menthol, trans-Menthole, L-Menthyl Acetate, (R)-p-Mentha-1,8-diene, Pin-2(3)-ene, p-Cymene, (S)-p-Menthal, S,diene, Geraniol)
Potassium Acesulfame
Menthol
Sodium Sacharin
Methyl Salicylate
Neohesperidin Dihydrochalcone
Lactic Acid

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.

Shelf-life after opening 21 days.

6.4 Special precautions for storage

Do not store above 25°C.
Protect from light

6.5 Nature and contents of container

Red coloured PET bottle, with a white coloured PP cap.

Each bottle contains 200 ml or 500 ml. Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

None.

7. MANUFACTURER

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Barcelona,
Spain

8. MARKETING AUTHORISATION HOLDER

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9. MARKETING AUTHORISATION NUMBER(S)

161-50-35132-00

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