SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Chlorhexidine Lacer Gel

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Chlorhexidine Digluconate 0.2% w/w
(equivalent to Chlorhexidine Digluconate Solution Ph. Eur. 1.06 % w/w)

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

3. PHARMACEUTICAL FORM

Oromucosal gel.

It is a transparent gel with characteristic odour.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

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

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 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.

Do not exceed the stated dose.

Children and Elderly patients:

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:

For oral (external) use only.

4.3 Contraindications

Chlorhexidine Lacer Gel is contraindicated for patients who have previously shown a hypersensitivity reaction to Chlorhexidine or to any of the excipients in the formulation (listed in section 6.1).

4.4 Special warnings and precautions for use

For oral 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.

Chlorhexidine Lacer Gel is incompatible with anionic agents which are usually present in conventional dentifrices. These should therefore be used before Chlorhexidine Lacer Gel (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. Stained anterior tooth coloured restorations with poor margins or rough surfaces which are not adequately cleaned by professional prophylaxis may require replacement.
PEG-40 Hydrogenated Castor Oil which 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 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.

Reporting of suspected adverse reactions

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://sideeffects.health.gov.il

4.9 Overdose

Accidental ingestion: Chlorhexidine taken orally is poorly absorbed. Systemic effects are unlikely even if large amounts 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: Antiinfectives and antiseptics for local oral treatment. ATC code: A01AB03

Mechanism of action:

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 bonds strongly to skin, mucosa and other 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

Propylene Glycol
Glycerin
Sorbitol
Hydroxyethylcellulose
PEG-40 Hydrogenated Castor Oil
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)
Menthol
Potassium Acesulfame
Methyl Salicylate
Water

6.2 Incompatibilities

Hypochlorite bleaches may cause brown stains to develop in fabrics which 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 4 weeks.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Aluminium tube with HDPE screwcap. The cannula used as applicator and corresponding cap are made of LDPE. Tube size 50 ml

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6.6 Special precautions for disposal and other handling

None.

7. MANUFACTURER

Lacer S.A.

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Barcelona,

Spain

8. MARKETING AUTHORISATION HOLDER

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Haifa Bay 2624761

Israel

9. MARKETING AUTHORISATION NUMBER(S)

161-51-35133-00

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