

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed without a doctor's prescription

Chlorhexidine Lacer Gel

Name and concentration of active ingredient: chlorhexidine digluconate 0.20% w/w

Inactive ingredients and allergens: see section 2 'Important information about some of this medicine's ingredients' and section 6 'Additional information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine is intended for use in patients over 12 years old. Consult your doctor before use in younger patients.

Use this medicine according to the instructions in the section about dose in this leaflet. Consult your pharmacist if you need further information. Consult your doctor if your symptoms of illness get worse or do not improve.

1. What is this medicine intended for?

- As an aid in the treatment and prevention of gum inflammation (gingivitis).
- For use following dental surgery or treatments, to promote healing of the gums.
- For use in mouth ulcers, inflammations due to dentures, and oral thrush.
- As an aid to maintaining oral hygiene.
- Inhibition of formation of dental plaque.

Therapeutic group: antiseptic

2. Before using this medicine

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the other

ingredients that this medicine contains. See section 6 'Additional information' for a list of inactive ingredients.

Special warnings regarding use of this medicine

- **Do not use anywhere other than in your mouth.** Do not swallow. In case of contact with the eyes or ears, rinse thoroughly with water.
- **In case of a severe allergic reaction, stop using this medicine and get help immediately.** See 'Side effects'.
- **Do not use immediately after you brush teeth.** See 'How to use this medicine' for more information.
- **Do not bleach fabrics** that have come into contact with this gel.
- **Temporary staining may appear on your teeth and tongue.** See 'Side effects'.
- You may experience a change in your sense of taste or you may feel stinging. See 'Side effects'.

When you use Chlorhexidine Lacer Gel to help treat or prevent gingivitis, your gums may bleed while you brush teeth.

Children and adolescents

This medicine is intended for use in patients over 12 years old. Do not use in children under 12 years old unless recommended by your doctor.

Drug interactions

If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist.

Pregnancy and breastfeeding

You may use this medicine if you are pregnant or breastfeeding.

Important information about some of this medicine's ingredients

This gel contains PEG-40 hydrogenated castor oil which may cause skin reactions.

3. How to use this medicine?

Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

Do not swallow. This medicine is for **use in the oral cavity only.**

Do not dilute.

Do not exceed the recommended dose.

Toothpaste may interfere with the Chlorhexidine Lacer Gel activity. So after brushing your teeth, rinse your mouth well with water and wait 5 minutes before using Chlorhexidine Lacer Gel, or use the gel at a different time of day than when you brush teeth.

The recommended dose is usually:

To treat gingivitis: After brushing your teeth, apply the gel directly onto the gum near the teeth (gingival sulcus) with the help of your finger or the nozzle. Gently massage with your fingertips to help adhere the gel, forming a thin protective film between the tooth and gum. The gel should be applied 2 or 3 times a day, after proper oral hygiene. Do not rinse after applying. Do not swallow.

To treat ulcers and oral thrush: Apply the gel directly to the painful areas using the tip of your finger or the nozzle, once or twice a day for at least one minute. Continue the treatment for two days after healing.

To treat denture-related inflammation in the mouth: Before inserting your dentures, gently apply the gel to the areas on the dentures that come into contact with the gums. Clean and soak your dentures in Chlorhexidine Lacer Mouthwash for 15 minutes twice a day or as instructed by your dentist.

As an aid in preventing dental caries or following dental surgery: Use as directed by your dentist.

If your symptoms persist, see your doctor.

If you have taken an overdose or if a child has accidentally swallowed some of the medicine, go immediately to a doctor or a hospital emergency room and bring the medicine package with you.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.

If you have any further questions regarding use of this medicine, consult your doctor or pharmacist.

4. Side effects

Like all medicines, using Chlorhexidine Lacer Gel may cause side effects in some users. Do not be alarmed by this list of side effects. You may not experience any of them.

Stop using the gel and seek immediate medical help if you get a **rash, swelling of your mouth or face**, or if you have **difficulty breathing**. These effects may be symptoms of a severe and very rare allergic reaction.

Stop using the medicine and **see your doctor** if you get **irritation of the mouth, soreness or swelling of the inside of the cheeks**.

Very common side effects - affect more than one in ten users

Temporary staining of the tongue. This disappears when treatment is stopped.

Common side effects - affect 1-10 in 100 users:

Dry mouth

You may notice a **change in your sense of taste, a burning sensation, numbness, or pricking in your tongue** when you first use the gel. This usually goes away with continued use. If the effects persist, consult your doctor.

Additional side effects

Temporary staining of the teeth. This can normally be removed by brushing. You can avoid staining by not drinking tea, coffee or red wine – especially one hour after use, and by brushing daily with toothpaste (see ‘How to use this medicine’). If staining remains it can be removed with a scale and polish from your dentist or hygienist. You may use denture cleaners to clean your dentures.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor, dentist, or pharmacist.

You can report side effects to the Ministry of Health by following the link ‘Reporting Side Effects of Medication’ on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link:

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

5. How to store the medicine?

Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place out of reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.

Do not use the medicine after the expiry date (exp. date) stated on the package. The expiry date refers to the last day of that month.

Storage conditions:

Store in the original package.

Do not store above 25°C

Use within 4 weeks of opening.

6. Additional information

In addition to the active ingredient this medicine also contains:

Propylene glycol, glycerin, sorbitol, hydroxyethylcellulose, PEG-40 hydrogenated castor oil, aroma (contains limonene, e-anethole, l-menthol, trans-menthole, l-menthyl acetate, (r)-p-mentha-1,8-diene, pin-2(3)-ene, p-cymene, (s)-p-mentha-1,8,diene, geraniol), menthol, potassium acesulfame, methyl salicylate, water.

What the medicine looks like and contents of the pack:

Clear gel packaged in a 50 ml aluminum tube, and an applicator.

Registration holder's name and address:

Taro International Ltd., 14 Hakitor St., Haifa Bay 2624761

Manufacturer's name and address:

Lacer S.A., Boters 5 parc tecnologic del valles, E-08290 Cerdanyola del valles, Barcelona, Spain

Revised in December 2021 according to MOH guidelines.

Registration number of the medicine in the Ministry of Health National Drug Registry:
161-51-35133-00