

Patient Leaflet According to the Pharmacists' Regulations (Preparations) – 1986

This medicine is sold without a doctor's prescription

**Kalgaron Mint
Kalgaron Strawberry
Kalgaron Orange
Lozenges**

Active ingredients:

Each lozenge contains:

Cetylpyridinium chloride (CPC) 1.25 mg and Lidocaine hydrochloride 1 mg.

For a list of the other ingredients, see section 6. See also 'Important information about some of the medicine's ingredients in section 2.

Read this entire leaflet carefully before using the medicine.

This leaflet contains concise information about the medicine. If you have any further questions, please refer to your doctor or pharmacist.

Use this medicine according to the instructions in the dosage section in this leaflet. Consult your pharmacist if you require additional information.

Refer to your doctor if the symptoms do not improve within 5 days, if they get worse or if you experience new symptoms.

This medicine is not intended for children under 6 years of age.

1. What is the medicine intended for?

This medicine is intended for the relief of severe sore throat and for relief of mouth and throat infections.

Therapeutic group:

Cetylpyridinium chloride - quaternary ammonium antiseptic.

Lidocaine - local anesthetic.

2. Before using the medicine

Do not use the medicine:

- If you are sensitive (allergic) to the active ingredients, to other anesthetics substances, to quaternary ammonium antiseptics, or to any of the other ingredients the medicine contains (for a list of the other ingredients, see section 6).
- In children aged under 6.

Special warnings regarding the use of this medicine:

- The anesthetic action of the medicine may interfere with swallowing and may cause inhalation of food (aspiration) during the meal (may be expressed as coughing), or cause you to bite your tongue. Therefore caution should be taken when using it. Likewise, do not use the medicine before eating or drinking. See also 'Use of the medicine and food' section.
- Do not use for more than 5 consecutive days, since this may modify the natural balance of flora in the mouth and throat (see also 'Side effects' section).
- Strictly follow the dosage instructions. Use of too much of the medicine, too frequent or prolonged use may cause neurological and cardiac disorders, as a result of absorption of the anesthetic substance into the bloodstream.
- Consult your doctor in case of fever, phlegm, discomfort in swallowing, in case of worsening or if there is no improvement after 5 days of treatment.
- The lidocaine in the medicine may lead to a positive result in the doping test sometimes administered to athletes.

Use in children:

This medicine is not intended for children under 6 years of age.
Caution should be exercised in use in children aged under 12.

Drug interactions:

If you are taking, or have recently taken any other medicines, including non-prescription medicines and nutrition supplements, please tell your doctor or pharmacist. Especially inform your doctor or pharmacist if you are using other medicines containing antiseptics and local anesthetics.

Use of the medicine and food

Do not eat or drink after using the medicine as long as the anesthetic effect exists. Therefore, do not use the medicine close to mealtimes. See also 'Warnings' above.

Pregnancy and breastfeeding:

If you are pregnant, plan to become pregnant or if you are breastfeeding, consult your doctor.

- It is recommended not to use this medicine during pregnancy.
- Do not use this medicine if you are breastfeeding, since the active ingredient lidocaine passes into the breast milk.

Important information about some of the medicine's ingredients:

- The medicine contains the sweetener xylitol and does not contain sugar; therefore, it is permitted for use by diabetics.
- Kalgaron lozenges contain coloring substances (see section 6). The coloring substances may cause allergic reactions.
- Kalgaron Mint contains about 12 mg lactose. If you have intolerance to certain sugars, inform your doctor before taking this medicine.

3. How to use this medicine?

Check with the doctor or pharmacist if you are not sure regarding the dosage and treatment regimen of the medicine.

- The lozenges are meant to be sucked on.
- Keep the lozenge in the mouth and let it dissolve slowly.
- Do not chew or swallow the lozenge.
- Do not use the medicine before eating or drinking. See also section 2.
- Make sure to keep an interval of at least two hours between one lozenge to the next.

Use in children aged 15 years and older, and in adults:

The standard dosage is usually:

One lozenge every 3 to 4 hours, as needed.

Do not exceed 6 lozenges in a 24 hour period.

Use in children (6-15 years of age):

The standard dosage is usually:

One lozenge every 3 to 4 hours, as needed.

Do not exceed 4 lozenges in a 24 hour period.

Do not exceed the recommended dosage.

- Check with your doctor or pharmacist if you are not sure.
- If there is no improvement in your condition within 5 days, or if there is any deterioration, refer to your doctor who may recommend additional treatment.
- Do not use the medicine for more than 5 consecutive days, without consulting your doctor.

If you have accidentally taken a higher dosage: if an overdose has been taken, go to a doctor or a hospital emergency room and bring the medicine package with you.

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

If you have further questions concerning the use of the medicine, consult your doctor or pharmacist.

4. Side effects

Like any medicine, the use of Kalgaron may cause side effects in some users. Do not be alarmed while reading the list of side effects, you may not suffer from any of them.

Stop using the medicine and refer to the doctor immediately if you experience an allergic reaction that can be expressed by the following side effects:

- Difficulty breathing or swallowing.
- Swelling of the face, lips, tongue or throat.
- Severe itching of the skin accompanied by red rash or skin bumps.

Stop the treatment and refer to your doctor in the following cases:

- If aspiration and impaired swallowing occur (see also warnings section).

Other side effects:

- Blisters in the mouth.
- Temporary numbness of the tongue (see also warnings section).

If a side effect appears, if any of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult with your doctor.

Reporting side effects:

Side effects may be reported to the Ministry of Health by clicking on the link "Report on side effects following medicinal treatment" on the homepage of the Ministry of Health website (www.health.gov.il) which leads you to the online form for reporting side effects, or by entering the link: <https://sideeffects.health.gov.il/>

5. How to store the medicine?

- Avoid poisoning! This medicine, and any other medicine, must be stored in a closed place out of the reach and sight of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the 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 below 25°C.

6. Additional information

- **In addition to the active ingredients, Kalgaron Strawberry also contains:**
Xylitol, cellulose microcrystalline, citric acid anhydrous, magnesium stearate, ponceau 4R lake, povidone K90, strawberry flavor.
- **In addition to the active ingredients, Kalgaron Mint also contains:**
Xylitol, cellulose microcrystalline, citric acid anhydrous, pigment blend green (contains brilliant blue, quinoline yellow, sunset yellow, lactose), magnesium stearate, povidone K90, frescofort flavor.
- **In addition to the active ingredients, Kalgaron Orange also contains:**
Xylitol, cellulose microcrystalline, citric acid anhydrous, magnesium stearate, povidone K90, orange flavor, sunset yellow AL lake E110.
- **What does the medicine look like and what does the package contain?**
Lozenges with an umbrella and 'RAFA' imprinted on one side.
Strawberry – pink, Mint – light green, Orange – orange.
The lozenges are packed in blisters, packs of 24 or 36 lozenges per box.
Not all package sizes may be marketed.

Registration holder: Rafa Laboratories Ltd., PO Box 405, Jerusalem 9100301.

Medicine registration number in the National Medicines Registry of the Ministry of Health:

Kalgaron Strawberry: 163-61-35351

Kalgaron Mint: 163-62-35352

Kalgaron Orange: 163-63-36018

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