

**PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS'
REGULATIONS (PREPARATIONS) – 1986**

The medicine is dispensed 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 the list of the additional ingredients, see section 6. See also "Important information about some of the medicine's ingredients" in section 2.

Read the entire leaflet carefully before using the medicine.

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

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

Refer to the doctor if the symptoms do not improve within 3 days, if they worsen or if you experience new symptoms.

This medicine is not intended for children under 12 years of age.

1. What is the medicine intended for?

The 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 anesthetic substances, to quaternary ammonium antiseptics, or to any of the additional ingredients the medicine contains (for a list of the additional ingredients, see section 6).
- In children under 12 years of age.

Special warnings regarding the use of the medicine:

- The anesthetic action of the medicine may interfere with swallowing and cause inhalation of food (aspiration) during the meal (may be expressed as coughing), or cause you to bite your tongue, and 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.
- Consult the doctor in case of fever, phlegm, discomfort swallowing, in case of worsening or if there is no improvement after 3 days of treatment.
- The lidocaine in the medicine may lead to a positive result in a doping (drugs) test sometimes administered to athletes.
- Caution should be exercised in cases of bleeding sores in the mucous membranes of the mouth - if you have to take the tablets, the sores could increase absorption of the active ingredients into the bloodstream. This is relevant especially among patients suffering from cardiovascular problems or with a tendency to muscle cramps.

- Caution is called for in cases of hepatic and/or renal insufficiency, as these restrictions may cause increased blood concentrations of the active ingredients.

Use in children

This medicine is not intended for children under 12 years of age.

Drug interactions

If you are taking, or have recently taken any other medicines, including non-prescription medicines and nutritional supplements, please tell the doctor or pharmacist. Especially inform the 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 are breastfeeding, consult the doctor or pharmacist. 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, and therefore, it is permitted for use by diabetics.
- Kalgaron lozenges contain coloring substances (see section 6). The coloring substances may cause allergic reactions.

3. How to use the medicine?

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

- The lozenges are meant to be sucked on.
- Keep the lozenge in the mouth and let it dissolve slowly in the mouth.
- 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 12 years and older, and in adults:

The standard dosage is usually: one lozenge every 3 to 4 hours, as needed. Do not use more than 6 lozenges in 24 hours.

Do not exceed the recommended dose.

- Check with the doctor or pharmacist if you are not sure.
- If there is no improvement in your condition within 3 days, or if there is any deterioration, refer to the doctor who may recommend additional treatment.
- Do not use the medicine for more than 3 consecutive days without consulting the doctor.

If you have accidentally taken a higher dosage: if an overdose has been taken, refer 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 the doctor or pharmacist.

4. Side effects

As with 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 a doctor 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 a red rash or skin bumps.

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

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

Additional side effects:

- Local irritation.
- Risk of bleeding if there is a recent mouth sore.

Rare side effects (appear in less than 1-10 users out of 10,000):

- Numbness in the tongue.
- Change in the sense of taste.

Very rare side effects (appear in less than 1 user out of 10,000):

Hypersensitive reaction or increase in sensitivity in the mouth (these side effects usually disappear rapidly).

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 the doctor.

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 green E-mix (E104, E133), 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, in packs of 24 lozenges per box.

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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