

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

The medicine is dispensed without a doctor's prescription

**Rogaron® Orange-Honey
Flavor
Lozenges**

**Rogaron® Lemon Flavor
Lozenges**

Composition

Each lozenge contains:

Benzylamine hydrochloride 3 mg

For information about 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.

Use this medicine according to the instructions provided in the dosage section of this leaflet. Consult your doctor or pharmacist if you need further information. Contact your doctor if disease symptoms get worse or do not improve after 3 days, or if you have fever or experience other symptoms.

1. What is this medicine intended for?

The medicine is intended for symptomatic local treatment of acute sore throat in adults and children above the age of 6 years.

Therapeutic group:

The active ingredient of the medicine is benzylamine, which is a local anti-inflammatory agent (NSAID).

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' and section 2.
- you suffer from a condition called phenylketonuria.
- you are sensitive (allergic) to salicylic acid or to other anti-inflammatory painkillers of the non-steroidal anti-inflammatory drug class (NSAIDs) such as ibuprofen.

Special warnings about using this medicine

❗ Before you start taking Rogaron, tell your doctor if:

- you have a history of asthma.
- you have an intolerance to certain sugars.

If after using this medicine, the pain in your mouth or throat gets worse or does not improve within 3 days, or if you have fever or have other symptoms, you should consult your doctor or pharmacist.

❗ Children and adolescents:

This medicine is intended for adults and children above the age of 6 years. In children aged 6-11 years, this medicine should be administered under an adult's supervision.

❗ Drug interactions:

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

Rogaron is not expected to affect other medicines. However, if you are not sure, ask your doctor or pharmacist about other nonprescription medicines.

❗ Using this medicine and food:

Food and drink have no influence on the medicine.

❗ Pregnancy and breastfeeding:

Do not use this medicine during pregnancy.

Do not use this medicine while breastfeeding.

❗ Driving and using machines:

This medicine has no effect or a negligible effect on your ability to drive or operate machines.

❗ Important information about some of this medicine's ingredients:

- This medicine contains isomalt (which is a type of sugar). If you have been told by your doctor that you have an intolerance (sensitivity) to certain sugars, consult your doctor before taking this medicine.
- This medicine contains 3.409 mg aspartame in each lozenge. Aspartame is a source of phenylalanine, which may cause damage to people with phenylketonuria (PKU), a rare genetic disease associated with phenylalanine accumulation, since the body cannot eliminate it properly.
- Rogaron Orange-Honey Flavor contains a red colorant (cochineal Red E-124) which may cause allergic 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 use this medicine.

The recommended dosage is usually:

Adults and children over the age of 6 years: one lozenge 3 times per day. Do not take more than 3 lozenges per day.

Use in children: In children aged 6-11 years, the medicine should be used under an adult's supervision.

Do not administer the medicine to children under the age of 6 years.

Do not exceed the recommended dose.

Manner of use:

- Suck the lozenge and let it dissolve slowly in your mouth.
- Do not swallow, split or crush and do not chew.
- Do not use this medicine for more than 7 days.

If after 3 days of using this medicine, your throat pain gets worse or does not improve, consult your doctor or pharmacist.

If you have accidentally taken a higher dose, if you have taken an overdose or if a child has accidentally swallowed some medicine, immediately see a doctor or go to 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 the medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

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

Allergic reactions are rare, but may be serious. Contact your doctor immediately if you get any sudden swelling in the mouth/throat, difficulty breathing, rash or itching, especially if affecting the whole body.

Uncommon side effect (may affect up to 1 in 100 users):

- Skin sensitivity to sunlight (causing a rash or sunburn).

Rare side effect (may affect up to 1 in 1,000 users):

- Burning sensation or dryness of the mouth. In such case, you can drink a glass of water to reduce these effects.

Very rare side effects (may affect up to 1 in 10,000 users):

- Sudden swelling in the mouth/throat and mucous membranes (angioedema).
- Difficulty breathing.

Side effects of unknown frequency (the frequency of these effects has not been established yet):

- Local loss of sensitivity of the oral mucosa
- Allergic reaction (hypersensitivity)
- Serious allergic reaction (anaphylactic shock). The signs may include difficulty breathing, chest pain or chest tightness, and/or feeling dizzy/faint, severe itching of the skin or raised lumps on the skin, swelling of the face, lips, tongue and/or throat, which may be life-threatening.

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.

Reporting side effects

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.
- **Store in a dry place, below 25°C.**
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines which are no longer used. These measures will help to protect the environment.

6. Additional information

In addition to the active ingredient, Rogaron lozenges also contain:

Rogaron Orange-Honey Flavor:

Isomalt, citric acid monohydrate, orange flavor, aspartame, honey flavor, peppermint oil, quinoleine yellow, cochineal red.

Rogaron Lemon Flavor:

Isomalt, citric acid monohydrate, Lemon flavor, aspartame, peppermint oil, quinoleine yellow.

What the medicine looks like and what are the contents of the package:

Rogaron Orange-Honey Flavor: a round orange colored lozenge.

Rogaron Lemon Flavor: a round yellow colored lozenge.

The lozenges are packed in blisters, each pack contains 20 lozenges.

Registration holder's name and address: Abic Marketing Ltd., POB 8077, Netanya.

Manufacturer's name and address: Teva Pharmaceutical Industries Ltd., POB 3190, Petach Tikva.

The leaflet was approved in April 2020.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:

Rogaron Orange-Honey Flavor:

164.23.35302.00

Rogaron Lemon Flavor: 164.22.35301.00

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