SUMMARY OF PRODUCT CHARACTERISTICS

Rogaron® Orange-Honey flavor
Rogaron ® Lemon flavor

1 NAME OF THE MEDICINAL PRODUCT

Rogaron® Orange-Honey Flavor
Rogaron® Lemon Flavor

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each lozenge contains 3 mg of benzydamine hydrochloride (equivalent to 2.68 mg of benzydamine).
Excipients with known effects:

- **Rogaron Orange-Honey:** each lozenge contains 2464.420 mg of Isomalt (E-953) and 3.409 mg of Aspartame (E-951) and 0.013 mg of Cochenille red colorant (E-124).
- **Rogaron Lemon:** each lozenge contains 2457.316 mg of Isomalt (E-953) and 3.409 mg of Aspartame (E-951) (lemon flavor).

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Lozenge.
Rogaron Orange-Honey: Round orange lozenges, 19 mm diameter, with orange and honey flavor.
Rogaron Lemon: Round yellow lozenges, 19 mm diameter, with lemon flavor.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Rogaron is indicated for symptomatic local treatment of acute sore throat in adults and children over 6 years of age.

Posology and method of administration

Posology

Adults and children over 6 years of age: one lozenge 3 times a day.
The treatment must not exceed 7 days.

Pediatric population

Children 6-11 years of age:
The medicinal product should be administered under adult supervision.
Children below 6 years of age:
Due to the type of the pharmaceutical form, the administration should be restricted to children of more than 6 years of age.

Method of administration

For oropharyngeal use.
Lozenge should be dissolved slowly in the mouth
patients should not swallow or chew the lozenges.

4.2 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.3 Special warnings and precautions for use

Benzydamine use is not advisable in patient with hypersensitivity to salicylic acid or other NSAIDs.

Bronchospasm may be precipitated in patients suffering from or with a previous history of bronchial asthma. Caution should be exercised in these patients.

In a minority of patients, buccal/pharyngeal ulceration may be caused by serious disease processes. Patients whose symptoms worsen or do not improve within 3 days, appear feverish or have other symptoms, must therefore seek the advice of their doctor or dentist as appropriate.

- The medicinal product contains isomalt and patients with rare hereditary problems of fructose intolerance should not take this medicine.
- This medicine contains 3.409 mg aspartame in each lozenge. Aspartame is a source of phenylalanine. It may be harmful for patient who have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.
- Rogaron Orange-Honey contains Cochinille red colorant (E-124) which may cause allergic reactions.

4.4 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

4.5 Fertility, Pregnancy and lactation

Pregnancy

There are no data from the use of benzydamine in pregnant women, and animal studies are insufficient with respect to reproductive toxicity (see section 5.3).

Rogaron lozenges should not be used during pregnancy.

Breastfeeding

There is insufficient information on the excretion of benzydamine in human milk.

Rogaron lozenges should not be used during breastfeeding.

4.6 Effects on ability to drive and use machines

Rogaron has no or negligible influence on the ability to drive and use machine, when it is used at the recommended dose.

4.7 Undesirable effects

Within each frequency grouping, undesirable effects are presented in order of decreasing seriousness

The following rate values have been used: Very common (≥ 1/10), Common (≥ 1/100 to <1/10), Uncommon (≥1/1,000 to <1/100), Rare (≥1/10,000 to <1/1,000) and Very rare (<1/10,000), not known (cannot be estimated from the available data).

System-Organ Class	Frequency	Undesirable effect
Immune system disorders	*Not Known*	Anaphylactic reaction, Hypersensitivity reaction
Respiratory, thoracic, and mediastinal disorders	*Very rare*	Laryngospasm
Gastrointestinal Disorders	*Rare*	Burning mouth, Dry mouth
	Not Known	Hypoaesthesia oral

Skin and subcutaneous tissue disorders	*Uncommon*	Photosensitivity
	Very rare	Angioedema

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

4.8 Overdose

Symptoms
No overdose with the lozenge formulation has been reported. However, very rarely in children excitation, convulsions, sweating, ataxia, tremor and vomiting have been reported after the oral administration of benzydamine dosages about 100 times higher than those of the lozenge.

Management
In the event of acute overdose, only symptomatic treatment is possible; the stomach should be emptied by inducing vomiting or by gastric lavage, and the patient carefully observed and given supportive treatment. Adequate hydration must be maintained.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: other agents for oral local treatment, *ATC code: A01AD02*.
Clinical efficacy and safety
Clinical studies demonstrate that benzydamine is effective in relieving suffering from localized irritation processes of the mouth and pharynx. In addition, benzydamine possesses a moderate local anaesthetic effect.

5.2 Pharmacokinetic properties

Absorption
The absorption through the mucosa of the mouth and pharynx was demonstrated by the presence of measurable quantities of benzydamine in the human plasma.
Distribution
About 2 hours after the 3 mg lozenge administration, benzydamine peak plasma values of 37.8 ng/ml with an AUC of 367 ng/ml*h were observed. However, these levels are not sufficient to produce pharmacological systemic effects.
When locally applied benzydamine has been shown to accumulate in inflamed tissues where it reaches effective concentrations because of its capacity to penetrate the epithelial lining.

Biotransformation and elimination
The excretion occurs mainly in the urine and mostly in the form of inactive metabolites or conjugation products.

5.3 Preclinical safety data

Development and peri-post natal toxicity was seen in reproductive toxicity studies in rats and rabbits at plasma concentration much higher (up to 40 times) than those observed after a

single therapeutic oral dose. No teratogenic effects were seen in those studies. Available kinetic data do not allow to establish the clinical relevance of the reproductive toxicity studies. As the preclinical studies had shortcomings and therefore are of restricted value, they do not provide additional information relevant for the prescriber beyond that included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Rogaron Orange-Honey:

Isomalt (E-953)
Citric acid monohydrate
Orange flavor
Aspartame (E-951)
Honey flavor
Peppermint oil
Quinoline yellow (E-104)
Cochenille red colorant (E-124)

Rogaron Lemon:

Isomalt (E-953)
Citric acid monohydrate
Lemon flavor
Aspartame (E-951)
Peppermint oil
Quinoline yellow (E-104)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The expiry date of the product is indicated on the packaging materials.

6.4 Special precautions for storage

Store in a dry place below 25ºC.

6.5 Nature and contents of container

Aluminium blisters.
Packaging size: 20 lozenges.

6.6 Special precautions for disposal

No special requirements.
Any unused product or waste material should be disposed of in accordance with local requirements.

7 LICENCE HOLDER AND MANUFACTURER

License Holder

Abic Marketing Ltd. P.O.Box 8077, Netanya.

Manufacturer

Teva Pharmaceutical Industries Ltd. P.O.Box 3190, Petach-Tikva

8 REGISTRATION NUMBER

Rogaron orange - honey flavor: 164-23-35302-00
Rogaron Lemon Flavor: 164-22-35301-00

This leaflet was approved in April 2020.