SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

KALGARON Mint
KALGARON Orange
KALGARON Strawberry

Lozenges

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

The tablet contains cetylpyridinium chloride (CPC) 1.25 mg and lidocaine hydrochloride 1 mg.

For the complete list of the excipients, see section 6.1.

3. PHARMACEUTICAL FORM:

Lozenges

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

For the relief of severe sore throat. Relief of mouth and throat infections.

4.2. Dosage and method of administration

Oral.
For adults and children over the age of 6 years.

Dosage
One tablet to be sucked every 3 to 4 hours:

- Adults: do not take more than 6 tablets a day.

- Children from 6 to 15 years of age: do not take more than 4 tablets a day.

Method of administration
Suck the tablet slowly. Do not crunch or swallow it. Wait at least 2 hours between tablets.
Do not take the tablet near to meal times.

4.3. Contraindications

Children under the age of 6 years.
Kalgaron is contraindicated in case of known hypersensitivity to antiseptics in the quaternary ammonium class, local anesthetics or one of the excipients indicated in section 6.1.

4.4. Special warnings and precautions for use

Warnings
Possibility of swallowing the wrong way on account of anesthetizing of the junction between the digestive tract and the respiratory system:

- Use this medicine carefully in children under the age of 12 years.

- Do not use this medicine before meals or before drinking.

The indication is for a treatment lasting no more than 5 days since it might expose to an imbalance of the normal microbial flora of the mouth cavity with risk of bacterial or fungal dissemination.
Repeated or prolonged treatment on the mucous membrane may expose to the risk of toxic systemic effects of contact anesthetics (impairing of the central nervous system with convulsions, depression of the cardiovascular system).

- Kalgaron Mint contains about 12 mg of lactose. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Precautions for Use
If the symptoms continue beyond 5 days and/or there is accompanying fever, treatment options should be reevaluated.
Athletes should be aware of the fact that this medicine contains an active substance (Lidocaine) that might lead to a positive reaction in tests carried out in the context of anti-doping controls.

4.5. Interactions with other medicinal products and other forms of interaction

Inadvisable combinations

Local antiseptics (in particular anionic compounds)
In successive or concomitant use, taking into account possible drug interactions (antagonism, inactivation).

4.6. Pregnancy and breast-feeding

Pregnancy
There is no reliable data on teratogenic effects in animals.
In clinical practice, no particular malformative or fetotoxic effect has been evidenced to date. However, monitoring of pregnancies exposed to this medicine is insufficient for exclusion of all risks.
Consequently, as a precaution, it is preferable not to use this medicine during pregnancy.

Lactation
Kalgaron must not be taken during breast-feeding since the lidocaine passes into the milk.

4.7. Effects on ability to drive and use machines

Not applicable.

4.8. Adverse effects

Possibility of:
- Allergic reactions to the quaternary ammoniums, the local anesthetics;
- Appearance of bullous lesions in the oral mucous membrane (quaternary ammoniums);
- Temporary numbness of the tongue and swallowing the wrong way (see section 4.4);

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation 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/

4.9. Overdose

No overdose has been reported.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic class: THROAT PREPARATIONS, ATC code: R02A
This medicine contains a combination of two active substances:

- An antiseptic of the quaternary ammonium class: cetylpyridinium chloride.

- A local anesthetic: Lidocaine Hydrochloride.

5.2. Pharmacokinetic properties

Lidocaine
Lidocaine is rapidly absorbed by the mucous membranes and in the gastrointestinal tract. Lidocaine passes the placental barrier and passes into the mother's milk. Metabolic degradation of Lidocaine in the liver is rapid. Lidocaine and its metabolites are renally excreted, about 3% in the form of unchanged Lidocaine.

Cetylpiridinium
No information is available.

5.3. Preclinical safety data

No specific preclinical information is available.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Kalgaron Mint: Xylitol, cellulose microcrystalline, citric acid anhydrous, pigment blend green (contains brilliant blue, quinoline yellow, sunset yellow, lactose), magnesium stearate, povidone K90, frescofort flavor.

Kalgaron Orange: Xylitol, cellulose microcrystalline, citric acid anhydrous, magnesium stearate, povidone K90, orange flavor, sunset yellow AL lake E110 .

Kalgaron Strawberry: Xylitol, cellulose microcrystalline, citric acid anhydrous, magnesium stearate, ponceau 4R lake, povidone K90, strawberry flavor.

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 below 25°C.

6.5. Nature and contents of outer packaging

24 or 36 lozenges in blister packs.
Not all package sizes may be marketed.

6.6. Special precautions for disposal and other handling

No specific requirements.

7.REGISTRATION HOLDER:

Rafa Laboratories Ltd., P.O. Box 405, Jerusalem 9100301.

Registration numbers:

KALGARON Mint: 163-62-35352
KALGARON Orange: 163-63-36018
KALGARON Strawberry: 163-61-35351

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