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 12 years.

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

Adults and children from 12 years of age: do not take more than 6 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 12 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.In patients with known hypersensitivity to one of the ingredients or to other amide-type local anesthetics, since a cross-allergy with lidocaine hydrochloride may occur.

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

- 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).
- In case of bleeding sores in the mucous membranes, do not take the medicine, as absorption of the active ingredients may be increased. This applies particularly to patients with cardiovascular disorders.

- Caution in patients with hepatic and/or renal impairment, as these restrictions may cause increased blood concentrations of the active ingredients.

Precautions for Use
- If the symptoms continue beyond 3 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.
- 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.

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, take into account possible drug interactions (antagonism, inactivation).

4.6. Pregnancy and breast-feeding

Pregnancy
No clinical data exist on the use by pregnant women. Animal experiments on the impact on pregnancy, the development of the embryo, the development of the fetus and/or the postnatal development are insufficient. There is no indication of any risk or fetal injury. Caution is called for if used during pregnancy.

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

4.7. Effects on ability to drive and use machines

Kalgaron has no influence or a negligible influence on the ability to drive or to use machines.

4.8. Adverse effects
Possibility of:
- Allergic reactions to the quaternary ammoniums, the local anesthetics;
- Local irritation
- Risk of bleeding if there is a fresh wound in the mouth
- Aspiration and swallowing the wrong way (see section 4.4):

Rare (less than <1-10\10000):

- Alteration of sense of taste
- Numbness in the tongue

Very rare (less than <1\10000):

Hypersensitivity reactions or sensitization may appear in the mouth (Usually, these effects disappear rapidly).

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 case of overdose has been reported to date with these medicines or similar lozenges.
However, a lidocaine overdose by mouth is theoretically also possible and has been reported for other Galenic forms. The major symptoms deriving from toxic doses of lidocaine concern the CNS (Central Nervous System-specifically convulsions) and the heart conduction system.

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, approx. 90% of the available dose is inactivated. Because of a major liver first-pass metabolism effect, the bioavailability is only approx. 35%. Lidocaine and its metabolites are renally excreted, about 10% 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 lozenges in blister packs.

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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