1. NAME OF THE MEDICINAL PRODUCT

Kaloba® Syrup

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

100 g (= 93.985 ml) contain 0.2506 g dry extract from Pelargonium sidoides - roots (1:8-10) (EPs™ 7630). Extraction agent: 11% ethanol (w/w) 20 mg/ 7.5ml

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Kaloba Syrup is an orange to light brown, viscous syrup.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

- Symptomatic treatment of acute bronchitis for adults and children form age of 1 years.
- Traditional herbal medicinal product for use in the common cold for adults and children from age of 1 years.

4.2 Posology and method of administration

Posology

Adults and adolescents over the age of 12:	7.5 ml syrup three times per day.
Children aged between 6-11 years:	5 ml syrup three times per day.
Children aged between 1 - 5 years:	2.5 ml syrup three times per day.

Use in children under the age of one is not recommended as there are no adequate data.

Method of administration
Oral administration.
Kaloba Syrup is to be taken mornings, at midday and evenings.
A measuring cup with various markings is enclosed for dosing Kaloba Syrup.
The cup should be cleaned appropriately after use.

Continuation of treatment is recommended for several days after relief of symptoms, in order to prevent a relapse.
If the symptoms become worse or no improvement occurs after 7 days, a doctor must be consulted.
Treatment should not exceed 3 weeks.

4.3 Contraindications

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

Kaloba syrup should not be taken in cases of severe hepatic diseases, as no sufficient experience is available in this area.

A doctor must be consulted if the condition does not improve within one week, with liver dysfunctions of different origin, or if fever, shortness of breath or bloody sputum occur. Cases of liver damage and hepatitis have been reported in connection with the use of medicinal products containing Pelargonium, no casual relationship with the use of Kaloba syrup, has been established.

Paediatric population:
Use in children under the age of one is not recommended as there are no adequate data.
For children under the age of two, a medical examination to determine the clinical picture should be undertaken prior to administration owing to the generally higher risk due to respiratory tract diseases.
For children between two and four years, a prior medical examination is necessary if they suffer from persistent or recurrent coughing.

4.5 Interactions with other medicinal products and other forms of interaction

None known to date.
In a placebo-controlled double-blind study in healthy volunteers, no interactions between the active substance in Kaloba® syrup for children and penicillin V were found.
There are no further investigations into interactions

4.6 Fertility, pregnancy and lactation

Pregnancy:
Kaloba Syrup should not be taken during pregnancy as there is no sufficient experience available.
Lactation:
Kaloba Syrup should not be taken during Lactation as there is no sufficient experience available
It is not known whether ingredients of the dry extract of *Pelargonium sidoides* roots or their metabolites pass into breast milk. A risk for the infant cannot be excluded.
Fertility:
There are no data about the effect on fertility in humans.
Animal experiments have shown no evidence of a harmful impact on fertility (see Section 5.3).

4.7 Effects on ability to drive and use machines

Kaloba Syrup has no, or only negligible, influence on the ability to drive or use machines.

4.8 Undesirable effects

The following classification is used for the frequency of adverse reactions:

Very common:	more than 1 in 10 treated persons
Common:	1 to 10 in 100 treated persons
Uncommon:	1 to 10 in 1,000 treated persons
Rare:	1 to 10 in 10,000 treated persons
Very rare:	less than 1 in 10,000 treated persons
Not known:	cannot be estimated from the available data

Gastrointestinal complaints, such as stomach pain, heartburn, nausea or diarrhoea, are uncommon during the use of Kaloba Syrup.
In rare cases, slight gingival bleeding or nosebleeds may occur. Furthermore, hypersensitivity reactions (exanthema, urticaria, pruritus of the skin and mucous membranes) have been described in rare cases. Such reactions may occur even when taking the medicine for the first time.
In very rare cases, severe hypersensitivity reactions with facial swelling, dyspnoea and hypotension may occur.
Hepatic dysfunction of various aetiologies. No causal relationship with the use of Kaloba Syrup has been established. The frequency is not known.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continuous monitoring of the risk/benefit ratio 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:

http://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il

4.9 Overdose

No cases of overdose have been reported.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other cough and cold preparations, ATC code: R05X

Kaloba Syrup contains an extract from the roots of *Pelargonium sidoides*, a plant which is indigenous to South Africa.

In animal experiments, inhibition of “sickness behaviour” (unspecific illness symptoms occurring in the context of an infection) and antioxidant properties could be demonstrated after oral application of the extract in mice.

In vitro, the following effects have been verified for Kaloba® syrup:

Stimulation of unspecific defence mechanisms:

- stimulation of ciliary beat frequency of epithelial cells,
- modulation of interferon and proinflammatory cytokine synthesis,
- stimulation of activity of NK-cells
- stimulation of phagocytes, expression of adhesion molecules, chemotaxis.

Antimicrobial effects:

- moderate direct antibacterial and antiviral properties
- increase/inhibition of adhesion of A-streptococci to desquamated/living epithelial cells
- inhibition of ß-lactamase.

Cytoprotective properties:

- inhibition of human leukocyte elastase
- antioxidant properties.

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5.2 Pharmacokinetic properties

Kaloba® syrup is a complex mixture of many ingredients which, as a whole, are to be considered as the active substance. Pharmacokinetic data for the individual substances are not yet available.

5.3 Preclinical safety data

Preclinical data reveal no particular hazards for humans.

Owing to the many years of medical use and comprehensive toxicological investigations on safety pharmacology, repeated dose toxicity, genotoxicity and reproduction and developmental toxicity, there is an adequately proven safety of use in humans.

In vitro and *in vivo* mutagenicity studies (Ames test, chromosome aberration test with human lymphocytes and the mouse micronucleus test) showed no evidence of a relevant genotoxic potential of the dry extract of *Pelargonium sidoides* roots (EPs 7630™) contained in Kaloba® syrup for children.

Reproduction-toxicological studies in rats (combined segment I and segment II, segment III) and in rabbits (segment II) showed no evidence of impairment of fertility, embryo-foetal development or peri-/postnatal development. Data from long-term studies on carcinogenic properties are not available

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

xylitol, glycerol 85%, Maltodextrin, potassium sorbate, xanthan gum, anhydrous citric acid, purified water

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

Storage condition: Do not store above 30°C
Note for storage after opening: Do not store more than 6 months and above 30°C.
Bottles should be stored vertically, do not store in a lying position or upside down.

6.5 Nature and contents of container

Brown glass bottle with pourer (polyethylene), screw cap (polyethylene/polypropylene) and measuring cup (polypropylene)
Pack sizes: Packs of 100 ml.

6.6 Special precautions for disposal and other handling

No special requirements.

7. ISRAELI MARKETING AUTHORIZATION HOLDER

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Israel
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8. **MANUFACTURER**:

Dr. Willmar Schwabe GmbH & Co. KG
Willmar-Schwabe-Str. 4
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GERMANY

9. MARKETING AUTHORISATION NUMBER

162-31-35357-00

10. DATE OF FIRST AUTHORISATION

January 2019

11. DATE OF REVISION OF THE TEXT

January 2019

12.GENERAL CLASSIFICATION FOR SUPPLY

Over the counter (OTC), For sale in pharmacies only.

KALOBA SYRUP SPC1219