Summary of Product Characteristics

1. NAME OF THE MEDICINAL PRODUCT

Kaloba tablets® film-coated tablets

For adults, adolescents and children over the age of 6 years

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 film-coated tablet contains:
Dried liquid extract of Pelargonium sidoides roots (1: 8- 10) (EPs® 7630) 20 mg
Extraction agent: ethanol 11 % (w/w)

For full list of excipients see section 6.1.

3. PHARMACEUTICAL FORM

Film-coated tablet

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

-Symptomatic treatment of acute bronchitis
- Traditional herbal medicinal product for use in the common cold

4.2. Posology and method of administration

Adults and adolescents over 12 years: 1 film-coated tablet 3 times daily
Children aged 6-12 years: 1 film-coated tablet twice daily

Tablets are taken with some liquid (preferably a glass of water) in the morning, midday and evening. Tablets are not to be taken in a lying position.

After symptoms subside, it is recommended to continue the treatment for several days in order to prevent a relapse. The duration of treatment should not exceed 3 weeks.

4.3. Contra-indications

Kaloba® tablets are not to be used in cases of hypersensitivity to one of the components of the pharmaceutical. Kaloba® tablets are not to be taken in cases of severe hepatic diseases as no sufficient experience is available in this respect.

4.4. Specials warnings and precautions for use

A doctor is to be consulted immediately if the condition does not improve within one week, in cases of fever lasting for several days or in cases of shortness of breath or bloody sputum.
Cases of liver damage and hepatitis have been reported in connection with the use of medicinal products containing Pelargonium. Patients should be told to discontinue treatment with Kaloba® tablets immediately and to consult a doctor if signs indicating liver function disorders occur.
Kaloba® tablets are not to be used in children under the age of 6 years.
Patients with rare hereditary galactose intolerance, lactase deficiency or glucose-galactose malabsorption should not take Kaloba® tablets.

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 Kaloba® tablets and penicillin V arose.
There are no further investigations into interactions.

4.6. Fertility, pregnancy and lactation

Pregnancy:
As yet there is no experience with the use of Kaloba® tablets in pregnant women. Animal studies showed no evidence of direct or indirect effects detrimental to health with respect to reproduction toxicity (see section 5.3). As a matter of precaution, the use of Kaloba® tablets during pregnancy should be avoided.

Lactation:
It is not known whether ingredients of the Pelargonium sidoides root extract or their metabolites are excreted in breast milk. A risk for infants cannot be excluded. Kaloba® tablets should therefore not be taken during breastfeeding.

Fertility:
Animal experiments showed no evidence of fertility impairment (see section 5.3)

4.7. Effects on ability to drive and use machines

None known

4.8. Undesirable effects

The evaluation of adverse reactions is based on the following information on frequency:

Very common: More than 1 out of 10 treated persons	**Common:** 1 to 10 out of 100 treated persons
Uncommon 1 to 10 out of 1,000 treated persons	**Rare:** 1 to 10 out of 10,000 treated persons
Very rare: Less than 1 out of 10,000 treated persons	
Not known Cannot be estimated from the available data	

According to the longstanding experience with the application of Pelargonium preparations, the side effects described below may occur when taking medicines containing Pelargonium:

- During treatment with Kaloba® tablets, gastro-intestinal complaints such as stomach pain, heartburn, nausea or diarrhoea occur occasionally.

- In rare cases, mild bleeding from the gums or nose may occur. In addition, hypersensitivity reactions (exanthema, urticaria, pruritus of the skin and mucous membranes) have been described in rare cases. Such reactions may already occur on first taking the medicine.

- In very rare cases, severe hypersensitivity reactions with swelling of the face, dyspnoea and drop in blood pressure may occur.

- Cases of liver damage and hepatitis have been reported in connection with medicinal products containing Pelargonium; the frequency is not known. Increased liver values have been observed occasionally during treatment.

- Reduced platelet levels have been observed during treatment (frequency not known). These may however be caused by the underlying disease (see 4.1).

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

4.9. Overdose

No cases of overdosage have been reported to date.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group:
herbal medicinal product for acute bronchitis
ATC- code: R05CP05
other cough and cold preparations
ATC - code: R05X

Kaloba® tablets contain 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 antioxidative properties could be demonstrated after oral application of the extract in mice.
In vitro, the following effects have been verified for Kaloba® tablets:
Stimulation of unspecific defence mechanisms:
- stimulation of ciliary beat frequency of epithelial cells,
- modulation of interferon synthesis and proinflammatory cytokines,
- 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
- antioxidative properties.

5.2. Pharmacokinetic properties

Kaloba® tablets are a complex mixture of a multitude of components which, as a whole, are to be considered as the active substance. Pharmacokinetic data on the individual substances are not yet available.

5.3. Preclinical safety data

Based on many years of medicinal use and comprehensive toxicological investigations on safety pharmacology, toxicity with repeated dosage, genotoxicity and reproduction and developmental toxicity, there is adequate evidence about the safety of use in man.
In vitro and *in vivo* mutagenicity studies (Ames test, chromosome aberration test with human lymphocytes and mouse micronucleus test) showed no evidence of a relevant genotoxic potential of the Pelargonium sidoides root extract (EPs 7630®) contained in Kaloba® tablets.
In reproduction-toxicological studies in rats (combined segment I and segment II, segment III) and rabbits (segment II), no evidence of impairment of fertility, embryo-foetal development and peri- or postnatal development was observed. Data from long-term studies on carcinogenic properties are not available.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Maltodextrin, microcrystalline cellulose, lactose monohydrate, croscarmellose sodium, precipitated silica, magnesium stearate (Ph. Eur.), hypromellose 5 mPas, macrogol 1500, iron oxide yellow E172, ironoxide red E172, titanium dioxide E171, talc, simeticone, sorbic acid (Ph. Eur.), methylcellulose.

6.2. Incompatibilities

No data necessary

6.3. Shelf-life

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

6.4. Special precautions for storage

Store below 30 ºC.

6.5. Nature and contents of container

Blisters made of PVC/PVDC foil and aluminium foil.
Original packs with 15, 21 or 30film-coated tablets.
Not all pack sizes may be marketed.

6.6. Special precautions for disposal

No special requirements

7. ISRAELI MARKETING AUTHORIZATION HOLDER

Dr. Samuelov Importing & Marketing Ltd.
13 Hasadna st, POB 2486
Ra'anana 4365007
Israel
Phone: 09 7483769

8. MANUFACTURER:

Dr. Willmar Schwabe GmbH & Co. KG
Willmar-Schwabe-Strasse 4
76227 Karlsruhe
Germany

9. MARKETING AUTHORIZATION NUMBER

160-53-34993- 00

9. DATE OF FIRST AUTHORIZATION/RENEWAL OF AUTHORIZATION

May 2018

10. DATE OF (PARTIAL) REVISION OF THE TEXT

Revised in June 2021 according to MOHs guidelines

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