

**Patient Package Insert according to Pharmacists' Regulations (Preparations) - 1986**

The medicine can be sold without a doctor's prescription

## Kaloba® Tablets

### Film-coated tablets

**Active ingredient and its quantity per dosage unit:**

**Each 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 a list of all inactive ingredients and allergens in the medicine – see section 6.

For important information about some of the ingredients of the medicine – see section 2.

**Read this leaflet carefully in its entirety before using the medicine.**

This leaflet contains concise information about the medicine. If you have any further questions, refer to the doctor or pharmacist.

The medicine Kaloba tablets is intended for adults, adolescents and children over 6 years of age.

You must take the medicine according to the instructions in the dosage section of this leaflet.

Consult the pharmacist if you need further information.

You must refer to the doctor if there is no improvement in your condition or if your condition has worsened after 7 days of using the medicine.

#### 1. What is the Medicine Intended for?

**The medicine Kaloba Tablets is intended:**

- for use during the common cold.
- for symptomatic treatment of acute bronchitis (inflammation of the bronchial tubes).

**Therapeutic group:** herbal medicine for the treatment of cough and the common cold. Common cold can be characterized with symptoms such as: cough, rhinitis, sore throat and elevated body temperature.

#### 2. Before Using the Medicine

**Do not use the medicine if:**

- you are hypersensitive (allergic) to the Pelargonium sidoides plant or to any of the additional ingredients contained in the medicine. The list of additional ingredients is detailed in section 6.
- you suffer from severe liver disease, since there is insufficient experience regarding use of the medicine in these cases.

**Special warnings regarding the use of this medicine:**

Refer to the doctor if there is no improvement in your condition or if your condition worsens after 7 days of using the medicine.

Refer to the doctor immediately in any case of fever that lasts for a number of days, shortness of breath or bloody sputum.

Stop using the medicine Kaloba Tablets and refer to the doctor if you develop symptoms that may indicate damage to liver function (e.g. yellowing of the skin and sclera or conjunctiva of the eye, dark urine, severe pain in the upper abdomen, loss of appetite).

**If you are taking or have recently taken any other medicines, including non-prescription medicines and nutritional supplements, tell your doctor or pharmacist.** So far, no interactions between Kaloba tablets and other medicines are known.

**Use of this medicine and food:**

The medicine Kaloba Tablets can be taken with or without food. Take the medicine with a

sufficient amount of a drinking liquid (preferably a glass of water).

**Pregnancy and breastfeeding:**

Do not use Kaloba Tablets while pregnant or breastfeeding since there is insufficient information regarding use during pregnancy and breastfeeding.

**Driving and use of machinery:**

Kaloba Tablets have no effect or have a negligible effect on the ability to drive or use machinery.

**Important information about some of the ingredients of this medicine:**

The medicine Kaloba Tablets contains lactose. You must consult a doctor before using the medicine if you have an intolerance to certain sugars.

#### 3. How Should You Use the Medicine?

Check with your doctor or pharmacist if you are not sure about the dosage and the manner of treatment with the medicine.

**The usual recommended dosage is:**

**In adults and adolescents over the age of 12:** one film-coated tablet 3 times a day.

**In children aged 6-12 years:** one film-coated tablet twice a day.

**Do not exceed the recommended dose.**

**Duration of treatment with the medicine Kaloba Tablets:** After symptoms abate, it is recommended to continue the treatment with the medicine Kaloba Tablets for a few more days, in order to prevent the return of the disease.

You must refer to the doctor if there is no improvement in your condition or if your condition worsens after 7 days of using the medicine.

Do not take the medicine Kaloba Tablets for more than 3 weeks.

**How to take the medicine Kaloba Tablets:** Swallow the film-coated tablet every morning, midday, and evening.

If you take the medicine twice a day, swallow the film-coated tablet every morning and evening. Swallow the film-coated tablet with a sufficient amount of drinkable liquid (e.g. a glass of water). Do not take the tablet while lying down.

Crushing/splitting/chewing: There is no information on crushing. Do not split the tablet since there is no score line.

**If you have accidentally taken a higher dosage** you must inform your doctor, who will decide whether it is necessary to take any action.

No specific symptoms are currently known in the case of taking an overdose.

If a child has accidentally swallowed the medicine, proceed immediately to a doctor or a hospital emergency room and bring the package of the medicine with you.

**If you forgot to take this medicine** at the intended time, do not take a double dose. Take the next dose at the usual time and consult your pharmacist or doctor.

**Do not take medicines in the dark! Check the label and dose each time you take a medicine. Wear glasses if you need them. If you have any further questions regarding the use of this medicine consult your doctor or pharmacist.**

#### 4. Side Effects

As with any medicine, the use of Kaloba Tablets may cause side effects in some users.

Do not be alarmed when reading the list of side effects. You may not experience any of them.

The list of the side effects detailed below includes all side effects reported during treatment with the Pelargonium sidoides plant root, including cases of higher dosage and long-term use.

**Very rare side effects (appear in less than one user out of 10,000) that require special attention:**

Stop using the medicine and seek medical assistance immediately if signs of hypersensitivity (allergic reaction) appear, such as:

Swelling of the face, breathlessness and a drop in blood pressure.

**Uncommon side effects that appear in 1-10 out of 1000 users of the medicine:**

Gastrointestinal discomfort e.g. abdominal pain, heartburn, nausea or diarrhea. Increase in liver values.

**Rare side effects (appear in 1-10 out of 10,000 users of the medicine):**

Skin hypersensitivity (rash, urticaria, itching of the skin and mucosal membranes), mild bleeding from the gums or nose.

These symptoms may also appear when the medicine is taken for the first time..

**Side effects of unknown frequency:**

Hepatic impairment and jaundice, no link was found between these side effects and taking the medicine Kaloba.

Low blood platelet count. The reason for this may be an existing background sickness e.g. common cold or bronchitis.

**If a side effect appears, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, you must refer to your doctor.**

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the home page of the Ministry of Health's website ([www.health.gov.il](http://www.health.gov.il)), which refers to the online form for reporting side effects or via the following link: <https://sideeffects.health.gov.il>

#### 5. How to Store the Medicine

• Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach of children and/or infants to avoid poisoning.

Do not induce vomiting unless explicitly instructed to do so by the doctor.

• Do not use this medicine after the expiry date (exp. date) stated on the carton box and/or on the blister.

The expiry date refers to the last day of that month.

• Storage conditions: store below 30°C.

#### 6. Additional Information

**In addition to the active ingredients, the medicine also contains the following inactive ingredients:**

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

**What the medicine looks like and the contents of the pack:** The medicine Kaloba Tablets looks like a round, brown-red, film-coated tablet, without a score line.

The film-coated tablets are packed in plastic trays (blisters), which are packed in carton boxes.

**Package size:** The medicine Kaloba Tablets is supplied in a carton package containing plastic trays containing 15 or 21 film-coated tablets.

There are packages which contain 15, 21 or 30 film-coated tablets. Not all package sizes may be marketed

**License holder and importer:** Dr. Samuelov Importing & Marketing Ltd., Company ID 512260944, P.O.B 2486, Ra'anana 4365007, Tel.: 09-7483769

**Manufacturer:** Dr. Willmar Schwabe & Co. KG, Karlsruhe, Germany.

Revised in June 2021 according to MOH guidelines.

**Registration number of the medicine in the National Drug Registry of the Ministry of Health:** 160-53-34993-00

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