

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

The medicine can be sold without a doctor's prescription

Kaloba® Syrup

Active ingredient and its quantity per dosage unit:

Pelargonium sidoides roots (1:8-10) (EPs® 7630) dried liquid extract 20 mg/7.5 ml
Extracting agent: ethanol 11% (w/w)

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

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.

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 or your child's condition has worsened after 7 days of using the medicine.

1. What is the Medicine Intended for?

The medicine Kaloba Syrup is intended:

- for use during the common cold in adults and in children from the age of 1 year.
- for symptomatic treatment of acute bronchitis accompanied by cough and mucus production, in adults and in children from the age of 1 year.

Acute bronchitis is also called 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 or elevated body temperature.

2. Before Using the Medicine

Do not use the medicine if you or your child:

- 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.
- 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, in any case of fever that lasts for a

few days, shortness of breath or bloody sputum.

Stop using the medicine Kaloba Syrup 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.

Children and adolescents:

Do not use the medicine Kaloba Syrup in toddlers under the age of 1 year, since there is insufficient information regarding use of the medicine in these ages.

In children under 2 years of age, a doctor's examination must be performed before use, as a higher general risk exists in children of this age group in cases of respiratory tract diseases.

In children from 2 to 4 years old, if the child suffers from a persistent or recurring cough, a doctor's examination should be performed before use.

Drug Interactions:

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 Syrup and other medicines are known.

Use of this medicine and food:

There is no information regarding the impact of food on the use of this medicine.

Pregnancy and breastfeeding:

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

Driving and use of machinery:

Kaloba Syrup has no effect or has a negligible effect on the ability to drive and use machinery.

Important information about some of the ingredients of this medicine:

The medicine Kaloba Syrup contains xylitol. Each 2.5 ml syrup contains 0.027 carbohydrate conversion units.

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 years: 7.5 ml syrup 3 times a day.

In children aged 6-11 years: 5 ml syrup 3 times a day.

In children aged 1-5 years: 2.5 ml syrup 3 times a day.

Do not exceed the recommended dose.

Duration of treatment with the medicine Kaloba Syrup:

After symptoms abate, it is recommended to continue the treatment with the medicine Kaloba Syrup 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 or your child's condition or if your or your child's condition worsens after 7 days of using the medicine.

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

How to take the medicine Kaloba Syrup:

Swallow the medicine Kaloba Syrup every morning, midday, and evening.

Use the measuring cup supplied in the product pack.

Taking the appropriate dose of the medicine while using the measuring cup:

The measuring cup supplied in the product pack includes 4 calibrating marks, two of them situated on each side.

Open the bottle and carefully fill the measuring cup up to the mark of the dose which is appropriate for you or for your child according to age.

It is now possible to let the child drink directly from the cup. Make sure that the child is sitting in an upright position, in order to prevent suffocation while drinking the medicine.

Rinse the cup thoroughly with running water and dry it after each use.

In case you prefer to use a teaspoon, first measure the appropriate dose for your child using the measuring cup. Afterwards, the contents of the cup should be transferred to a teaspoon.

Make sure to close and screw the cap after each use of the medicine.

If you or your child 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. The side effects described in the side effect section may appear at a higher frequency. 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 Syrup 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 (appear in 1-10 out of 1,000 users of the medicine):

Gastrointestinal discomfort e.g. abdominal pain, heartburn, nausea or diarrhea.

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:

Increased liver values, hepatic impairment and jaundice have been reported following use of products containing the Pelargonium plant, the frequency is unknown.

No link was found between these side effects and taking the medicine Kaloba Syrup.

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), 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 and sight 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 bottle. The expiry date refers to the last day of that month.

Shelf life after first opening: 6 months.

The bottle should be stored vertically, do not store in a lying position or upside down.

Storage conditions:

do not store above 30°C.

Storage conditions after first opening: do not store above 30°C.

6. Additional Information

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

Xylitol, Glycerol 85%, Maltodextrin, Potassium sorbate, Xantan gum, Citric acid anhydrous, Purified water.

What the medicine looks like and the contents of the pack:

The medicine Kaloba Syrup looks like an orange to light brown, viscous syrup. The syrup is packed in carton box, containing a glass bottle, a white closure which includes a safety ring and a measuring cup.

Package size: The medicine Kaloba Syrup is supplied in a 100 ml volume bottle.

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: 162-31-35357-00

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