

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Kaloba Oral Drops, solution
Boots Herbal Cold Relief Oral Solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:

10 g (= 9.75 mL) of oral solution contains 8.0 g extract from the roots of *Pelargonium sidoides* DC (1 : 8 - 10) (EPs® 7630).

Extraction solvent: 11% ethanol (w/w).

1 ml (approximately 20 drops) of Kaloba Oral Drops, solution contains 120 mg ethanol (alcohol) equivalent to 2.4 ml beer or 1.0 ml of wine.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral drops, solution
Light brown to reddish brown solution

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Traditional herbal medicinal product used to relieve the symptoms of upper respiratory tract infections including common cold, such as sore throat, cough and blocked or runny nose, based on traditional use only.

4.2 Posology and method of administration

Adults and adolescents over the age of 12:

Take 30 drops three times per day.

Children aged between 6-12 years:

Take 20 drops three times per day.

The necessary amount of drops may be taken directly from a spoon or, if preferred, can be mixed with half a glass of water and the contents of the entire glass should be drunk straightaway.

The dose should be taken in the morning, at midday and in the evening.

20 drops is equivalent to approximately 1ml

30 drops is equivalent to approximately 1.5ml.

Duration of application

After relief of symptoms, continuation of treatment for further 2 – 3 days is recommended in order to prevent a relapse, however treatment duration should not exceed 2 weeks.

4.3 Contraindications

Kaloba is not to be used in the following cases:

- hypersensitivity to the active substance or to the excipient,
- increased tendency to bleeding and application of coagulation-inhibiting drugs,
- severe hepatic and renal diseases, as no adequate data are available in these areas,
- pregnancy and lactation
- children < 6 years.

4.4 Special warnings and precautions for use

In the package leaflet, the patient is advised to consult a doctor immediately if his or her condition does not improve within one week, in case of fever lasting for several days or in case of shortness of breath or bloody sputum.

Kaloba oral solution contains 12 vol % ethanol (alcohol).

This corresponds to:

- 180 mg alcohol equivalent to 3.6 ml beer or 1.5 ml wine per adults' single dose (30 drops)
- 120 mg alcohol equivalent to 2.4 ml beer or 1.0 ml wine per children's single dose (20 drops).

Harmful for those suffering from alcoholism. To be taken into account in children and high-risk groups such as patients with liver disease, or epilepsy.

4.5 Interaction with other medicinal products and other forms of interaction

Drug interactions have not been reported to date.

However, due to the potential influence of Kaloba on coagulation parameters, the possibility that this product enhances the effect of coagulation-inhibiting drugs such as warfarin in cases of simultaneous intake cannot be excluded (see section 4.3).

4.6 Pregnancy and lactation

This product should not be used in women who are pregnant or breast-feeding, as there are no data available for these patient groups.

4.7 Effects on ability to drive and use machines

Kaloba has no or negligible influence on the ability to drive and use machines.

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: more than 1 out of 100 treated persons
Uncommon: more than 1 out of 1000 treated persons	Rare: more than 1 out of 10 000 treated persons
Very rare: 1 or less out of 10 000 treated persons including single cases	

Gastro-intestinal complaints such as stomach pain, heartburn, nausea or diarrhoea may occur uncommonly ($\geq 1/1,000$ to $< 1/100$) during treatment with Kaloba.

In rare cases ($\geq 1/10,000$ to $\leq 1/1,000$), mild bleeding from the gingiva or nose may occur.

Furthermore, hypersensitivity reactions (e.g. exanthema, urticaria, pruritus of skin and mucous membranes) have been described in rare cases. Such reactions may already occur at the first intake of the pharmaceutical product.

In very rare cases ($\leq 1/10,000$), serious hypersensitivity reactions with swelling of the face, dyspnea and drop of blood pressure may occur.

In single cases, signs indicating disturbances of liver function have been reported after intake of Kaloba; the causal relationship between this effect and the application of the product has not been demonstrated.

4.9 Overdose

The effects of overdose are unknown.

Although there are no data on cases of overdose, overdose is likely to increase side effects. Thus, treatment should be symptomatic and as clinically indicated.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Not required.

5.2 Pharmacokinetic properties

Not required.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity and toxicity to reproduction.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol 85%

Ethanol

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Unopened:

2 years

In-use:

- for bottles with 20 ml and 50 ml: 3 months
- for bottles with 100 ml: 6 months

6.4 Special precautions for storage

Do not store above 30°C.

6.5 Nature and contents of container

Brown glass bottles, hydrolytic class III (Ph. Eur.), with dropper tip and screw cap (PP/PE), in pack sizes of 20 ml, 50 ml or 100 ml oral solution.

6.6 Special precautions for disposal and other handling

No special requirements.

7. MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER(S)

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9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

26th March 2008

10. DATE OF REVISION OF THE TEXT

4th August 2009