

**SUMMARY OF PRODUCT CHARACTERISTICS**

## **1. NAME OF THE MEDICINAL PRODUCT**

Kaloba film-coated tablets  
Boots Herbal Cold Relief film-coated tablets

## **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

1 film-coated tablet contains 20 mg of extract (as dry extract) from the roots of *Pelargonium sidoides* DC (1 : 8 - 10) (EPs<sup>®</sup> 7630)  
Extraction solvent 11% ethanol (w/w).

### *Excipient:*

One film-coated tablet contains 20 mg lactose monohydrate.

For a full list of excipients, see section 6.1.

## **3. PHARMACEUTICAL FORM**

Film-coated tablet  
Round, reddish-brown, smooth surface film coating without ruptures.

## **4. CLINICAL PARTICULARS**

### **4.1 Therapeutic indications**

Traditional herbal medicinal product used to relieve the symptoms of upper respiratory tract infections including the 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 12 years of age:*

Take 1 tablet three times daily (morning, midday, evening).

Tablets should be swallowed whole with a little water. The tablets should not be chewed.

The use in children under 12 years of age is not recommended (see section 4.4 'Special warnings and precautions for use').

#### *Duration of use:*

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

If the symptoms persist during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.

### **4.3 Contraindications**

Kaloba is not to be used in the following cases:

- hypersensitivity to the active substance or to any of the excipients,
- increased tendency to bleeding,
- patients using coagulation-inhibiting drugs,

- severe hepatic and renal diseases, due to lack of adequate data.

#### 4.4 Special warnings and special precautions for use

In the patient information 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 blood in the sputum.

One film-coated tablet contains 20 mg lactose monohydrate.

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

On theoretical grounds Kaloba should not be used where there is a likelihood of increased tendency to bleeding or use of coagulation-inhibiting drugs.

Kaloba should not be used in case of severe hepatic and renal diseases, due to lack of adequate data.

This formulation is not suitable for children under 12 years of age.

#### 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 effect of Kaloba on coagulation parameters, this product may enhance the effect of coagulation-inhibiting drugs such as warfarin and should not be taken concomitantly with these drugs. (see section 4.3).

#### 4.6 Pregnancy and lactation

Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended.

#### 4.7 Effects on ability to drive and use machines

No studies on the effect on the ability to drive and use machines have been performed.

#### 4.8 Undesirable effects

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

<b>Very common:</b> more than 1 out of 10 treated persons	<b>Common:</b> more than 1 out of 100 treated persons
<b>Uncommon:</b> more than 1 out of 1000 treated persons	<b>Rare:</b> more than 1 out of 10 000 treated persons
<b>Very rare:</b> 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 gums 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 occur after the first intake of the product.

In very rare cases ( $\leq 1/10,000$ ), serious hypersensitivity reactions with swelling of the face, dyspnoea and drop in 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 use of the product has not been demonstrated.

If other adverse reactions not mentioned above occur, a doctor or a qualified health care practitioner should be consulted.

#### **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**

Tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed.

### **6. PHARMACEUTICAL PARTICULARS**

#### **6.1 List of excipients**

*Extract:*

Maltodextrin

*Tablet core:*

Maltodextrin

Microcrystalline cellulose

Lactose monohydrate

Croscarmellose sodium,

Precipitated silica

Magnesium stearate

*Film-coating:*

Hypromellose 5 mPas

Macrogol 1500

Iron oxide yellow E172

Iron oxide red E172  
Titanium dioxide E171  
Talc  
Simeticone  
Methylcellulose  
Sorbic acid.

## **6.2 Incompatibilities**

Not applicable.

## **6.3 Shelf life**

4 years.

## **6.4 Special precautions for storage**

This medicinal product does not require any special storage conditions.

## **6.5 Nature and contents of container**

Cartons containing blister strips of 15 or 21 tablets. Kaloba is available in packs with 21, 30, 42, and 60 tablets. Not all pack sizes may be marketed.

## **6.6 Special precautions for disposal and other handling**

No special requirements.

## **7. MARKETING AUTHORISATION HOLDER**

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Distributed in the UK by:

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## **8. MARKETING AUTHORISATION NUMBER(S)**

THR 05332/0005

## **9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

31<sup>st</sup> March 2009

## **10. DATE OF (PARTIAL) REVISION OF THE TEXT**

9<sup>th</sup> July 2009