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The Medicines and Healthcare products Regulatory Agency (MHRA) granted Dr. Willmar Schwabe GmbH & Co. KG Ltd a Traditional Herbal Registration Certificate for the traditional herbal medicinal product Kaloba Oral Drops, solution (Traditional Herbal Registration number: THR 05332/0003). This product is available without prescription and can be bought from pharmacies and other outlets.

The active ingredient of Kaloba Oral Drops, solution comes from the roots of the plant *Pelargonium sidoides* DC. Kaloba Oral Drops, solution is a traditional herbal medicine used for the relief of the symptoms of upper respiratory tract infections, including common cold, such as sore throat, cough and blocked or runny nose. This registration is based exclusively upon the longstanding use of the extract from the roots of *Pelargonium sidoides* as a traditional herbal medicine and not upon data generated from clinical trials. There is no requirement under the Traditional Herbal Registration scheme to prove scientifically that the product works.

No new or unexpected safety concerns arose from this application and it was, therefore, decided that a Traditional Herbal Registration Certificate could be granted.
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INTRODUCTION

The MHRA granted a Traditional Herbal Registration Certificate for the traditional herbal remedy Kaloba Oral Drops, solution to Willmar Schwabe GmbH & Co. KG Ltd on 26 March 2008. This product is available without prescription and can be bought from pharmacies and other outlets.

This application was submitted according to Article 16.c of Directive 2001/83 EC, as amended, as part of the Traditional Herbal Medicines Registration Scheme.

The data supplied by the Applicant demonstrate 30 years of traditional use of *Pelargonium sidoides* root extract solution in the European Community. A satisfactory review of the available safety data on *Pelargonium sidoides* root extract has also been provided, together with an Expert Safety Report supporting the proposed product.
INTRODUCTION
This product is presented as an oral solution where 10g (= 9.75mL) of oral solution contains 8.0g extract from the roots of the *Pelargonium sidoides* (1:8-10) (EPs® 7630). The extraction agent is 11% w/w ethanol.

**Background information**
*Pelargonium* species are indigenous to an area in southern Africa and have been used as traditional medicines because of their astringent properties.

*Pelargonium sidoides* is a small geranium-like plant that grows in a rosette from thick, underground roots. It is mainly found growing inland in South Africa.

A *Pelargonium sidoides* root extract solution has been marketed in Germany for more than 50 years, where it has been used for the treatment of symptoms of the common cold. It is believed to demonstrate antimicrobial activity and may have a stimulatory effect on the immune system.

**HERBAL SUBSTANCE**

**General information**
Latin name: *Pelargonium sidoides* DC
Family: Geraniaceae
Parts of plant used: Roots (dried)
Origin: South Africa

**Manufacture**
The plant is grown in the wild or cultivated in South Africa. Plants grown in the wild are harvested from September through to April. Cultivated plants are collected after about 3 years of growth. The roots are washed, cut and dried.

A signed document has been provided confirming that the herbal substance is produced in line with the *Guideline on Good Agricultural and Collection Practice (GACP) EMEA/HMPC/246816/2005*. The declaration covers both cultivation on organically certified farms and wild harvested crops.

Official permission has been given to collect the plant from the wild. A signed declaration is provided from the supplier stating that herbal substance collected from the wild is free of other potentially contaminating species.

**Control of Herbal Substance**
The specifications of the herbal substance are in line with the European Pharmacopoeia monograph and are satisfactory.

Certificates of analysis are provided for batches of herbal substance, giving full results for test parameters to support the proposed specification.

**Reference Standards or Materials**
Satisfactory information has been provided on the reference standards used in the analysis of the herbal substance.

**Container Closure System**
A suitable container closure system is used to store the herbal substance and the containers are kept in appropriate conditions.

**Stability**
A confirmation is given that the herbal substance is tested prior to making the herbal preparation.

The herbal substance is stored according to Good Storage Practice under specified, controlled conditions, which exclude any negative impact on the quality of the material.

**HERBAL PREPARATION**
**General information**

*Liquid extract*
A light brown to reddish brown liquid.

**Manufacture**
A flow diagram of the manufacturing process of the herbal preparation has been provided.

Certificates of analysis for all materials used in the manufacture of the herbal preparation are provided. All excipients are tested and released according to their Ph. Eur. monograph.

Satisfactory in-process controls are in place during manufacture to ensure the quality of the herbal preparation.

**Control of Herbal Preparation**
A satisfactory specification with appropriate tests and limits has been provided for the herbal preparation.

Satisfactory analytical procedures are used to control the quality of the herbal preparation. Analytical procedures have been validated, as appropriate.

Certificates of analysis have been provided for production batches of the herbal preparation, demonstrating satisfactory compliance with the proposed specification.

**Container Closure System**
Satisfactory specifications have been provided by the supplier of the container closure system, together with a declaration of compliance with Directive 90/128 EC, as amended. Assurances have also been provided from the suppliers that the containers are suitable for food use.

**Stability**
Batches were packed in the container closure system and stored in ICH conditions. The data support the condition that the herbal preparation will be stored for no longer than 3 days and at temperatures not greater than 30°C.

**HERBAL PRODUCT**

**Description and Composition of the Herbal Product**

The product is a pale brown to reddish-brown oral liquid comprised of an ethanolic extract from the roots of *Pelargonium sidoides* (80%). The only other constituent is glycerol 85%, which complies with the Ph. Eur. reference standard, as does the ethanol which is present in the herbal preparation.

Satisfactory Certificates of Analysis of the excipients have been provided by the suppliers.

Confirmation is provided that glycerol is exclusively obtained from vegetable or mineral-synthetic origin and is not liable to TSE.

There are no overages in this product.

The stability data support the compatibility of the active with the selected excipients and the packaging.

**Manufacture**

The manufacturing method is a standard procedure which involves mixing the herbal preparation with 85% glycerol. A flow diagram summarising the manufacturing process and in-process controls has been provided. The liquid is filled into amber bottles, labelled and packed into cartons with a patient information leaflet.

In-process controls are appropriate considering the nature of the product and the method of manufacture. Process validation has been carried out on product batches and the results are satisfactory.

**Control of Herbal Product**

The finished product specifications at release and end of shelf life are detailed and the tests and limits used were found to be satisfactory for a product of this nature.

Full details of all analytical methods and validation data are provided. These are generally the same as those applied to the herbal preparation and are appropriate.

Batch data have been provided and comply with the release specification. Certificates of analysis have been provided for any working standards used.

**Reference Standards or Materials**

Satisfactory information has been provided on the reference standards used.

**Container Closure System**

The finished product is packed in class III brown glass bottles, with a dropper tip and screw cap (PP/PE). The bottles contain either 20 ml, 50 ml or 100 ml oral solution.
Satisfactory specifications and certificates are provided from the manufacturers of all components of the container. It is confirmed that the material from which the dropper insert is made complies with the Ph.Eur and is suitable for use with foodstuffs.

**Stability**

Stability studies were conducted under ICH conditions on product batches in the container type proposed for marketing.

Based on the results, a proposed shelf life of 2 years with the storage condition “Do not store above 30°C” is justified.

In-use stability studies were conducted under ICH conditions on product batches in the container type proposed for marketing. Based on the results, it was concluded that opened 20 ml and 50 ml bottles should be used within 3 months of opening and 100 ml bottles should be used within 6 months once opened.

**PRODUCT LITERATURE**

The product literature (Summary of Product Characteristics, Patient Information Leaflet and labelling) for this product are pharmaceutically satisfactory.

A package leaflet has been submitted to the MHRA along with results of consultations with target patient groups (“user testing”), in accordance with Article 59 of Council Directive 2001/83/EC. The results indicate that the package leaflet is well-structured and organised, easy to understand and written in a comprehensive manner. The test shows that the patients/users are able to act upon the information that it contains.

**ASSESSOR’S OVERALL CONCLUSIONS ON QUALITY**

This product is satisfactory and a Traditional Herbal Registration can be granted.
PRECLINICAL ASSESSMENT

PRECLINICAL SAFETY DATA
The Safety Expert Report submitted by the applicant lists relevant references to published work on the safety of *Pelargonium sidoides* extract. The report also includes the company’s own data on toxicity to reproduction and genotoxicity, as required in EMEA/HMPC/32116/2005 Guideline on Non-Clinical Documentation for Herbal Medicinal Products in Applications for Marketing Authorisation (Bibliographical and Mixed Applications). The author of the report has suitable expertise in pharmacology and toxicology. The report is dated April 2006.

NONCLINICAL OVERVIEW
A good review of the non-clinical literature on the active component of Kaloba Oral Drops, solution was provided and was presented as described in guideline EMEA/HMPC/32116/05. Some of the studies in the literature review were conducted and published before GLP was a regulatory requirement. Moreover, it is not possible to ascertain if the data assessed in the review would comply with today’s regulatory safety testing requirements with regards to design, conduct and analysis.

Due to a shortage of published data on *Pelargonium sidoides* root extract it is not possible to assess if the safety package for the phytochemical constituents of Kaloba Oral Drops, solution meets current standards of GLP and safety testing requirements. However, the information supplied demonstrating traditional use is acceptable and thus the lack of provision of a complete standard safety package is acceptable and in compliance with guideline EMEA/HMPC/32116/0.

SUMMARY OF PRODUCT CHARACTERISTICS
The preclinical sections of the Summary of Product Characteristics for this product are satisfactory.

ENVIRONMENTAL RISK ASSESSMENT
An environmental risk assessment is not required for herbal medicinal products according to guidance CPMP/SWP/4447/00.

CONCLUSION
The information supplied demonstrating traditional use of *Pelargonium sidoides* is acceptable. An adequate literature review for *Pelargonium sidoides* has been carried out by the applicant. Granting of a THR is acceptable.
CLINICAL ASSESSMENT

BACKGROUND INFORMATION
Pelargonium species are plants indigenous to Southern Africa that have been used as traditional medicines because of their astringent properties.

A Pelargonium sidoides extract solution has been marketed in Germany for more than 50 years, where it has been used for the treatment of symptoms of the common cold. Pelargonium sidoides extract is thought to demonstrate antimicrobial activity, it has also been claimed that it has a stimulatory effect on the immune system, though evidence for this is scant. The concentration required for bacteriostatic activity is considered to be too high to be of clinical relevance.

PROPOSED INDICATION
The applicant has proposed the following, which is satisfactory:

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.

EVIDENCE OF TRADITIONAL USE
Article 16 c 1 (c) requires the Applicant to provide bibliographic or expert evidence to show that the medicinal product in question, or a corresponding product has been in medicinal use throughout a period of at least 30 years, including at least 15 years within the Community.

The Applicant has provided a comprehensive bibliographic review which shows evidence for the use of Pelargonium sidoides extract solution within the EU for a period exceeding 30 years and has provided a discussion regarding the use of this product.

SAFETY REVIEW
Article 16 c 1 (D) requires the Applicant to provide a bibliographic review of the safety data, together with an expert report.

A safety review has been provided, along with an Expert Report written by a suitably qualified clinician.

The review is comprehensive and summarises all safety data (including that from the most recently published literature), both from the literature and based on post marketing surveillance.

PRODUCT LITERATURE
The product literature (Summary of Product Characteristics, Patient Information Leaflet and labelling) for this product are medically satisfactory.

The Patient Information Leaflet has been submitted to the MHRA along with results of consultations with target patient groups ("user testing"), in accordance with Article 59 of Council Directive 2001/83/EC. The results indicate that the package leaflet is
well-structured and organised, easy to understand and written in a comprehensive manner. The test shows that the patients/users are able to act upon the information that it contains.

**ASSESSMENT OF SUITABILITY FOR GSL STATUS**

Section 51 of the Medicines Act 1968 states that “GSL may be appropriate for medicines which can, with reasonable safety, be sold or supplied otherwise than by or under the supervision of a pharmacist”. The term “reasonable safety” may usefully be defined as: “Where the hazard to health and the risk of misuse and the need for special precautions in handling are small, and where wider sale would be a convenience to the purchaser”.

1. **Hazard to health**
   There appears to be a minimal risk of hazard to health.

2. **Risk of misuse**
   In essence the risk of misuse of this product is felt to be low.

3. **Need to take special precautions in handling**

4. **Wider sales are convenient to the purchaser**

In summary, it is considered that the four above criteria for GSL status have been met and this product should be suitable for GSL status. Due to a lack of data, this product is contraindicated in patients under the age of 6.

**DISCUSSION**

This is an application for registration under the Traditional Herbal Medicinal Products Directive.

The data supplied by the Applicant are sufficient to demonstrate 30 years of traditional use within the European Community as required for registration under the Traditional Herbal Medicines Product Directive. A satisfactory review of the available safety data relating to *Pelargonium sidoides* extract has been provided, along with an expert report supporting the registration of the product.

**RECOMMENDATIONS**

A Traditional Registration may be granted.
OVERALL CONCLUSION AND RISK ASSESSMENT

QUALITY
The quality data submitted with this application are satisfactory.

PRECLINICAL
Satisfactory preclinical data were submitted. A comprehensive bibliographic review of the current safety information is also provided.

EFFICACY AND SAFETY
No clinical efficacy data are required for registration of Traditional Herbal Medicinal Products (THMP).

The Applicant has provided a bibliographic review which shows ample evidence for the use of *Pelargonium sidoides* root extract within the EU for a period exceeding 30 years.

A satisfactory review of the safety data has also been provided.

The SPC, PIL and labelling are satisfactory.

RISK ASSESSMENT
The quality of the product is acceptable and no new preclinical or clinical safety concerns have been identified.
KALOBA ORAL DROPS, SOLUTION

THR 05332/0003

STEPS TAKEN FOR ASSESSMENT

1 The MHRA received the Traditional Herbal Registration application on 4 July 2006
2 Following standard checks and communication with the applicant the MHRA considered the application valid on 16 January 2007
3 Pharmaceutical, preclinical and clinical issues were raised in relation to this application at the Herbal Medicine Advisory Committee meeting on 28 March 2007
4 The applicant addressed the issues raised by the HMAC on 22 October 2007
5 Following assessment of the response the MHRA requested further information relating to the quality dossier on 27 November 2007
6 The applicant responded to the MHRA’s requests, providing further information on the quality dossier on 17 December 2007 and 3 March 2008
7 A THR was granted on 26 March 2008
SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT
Kaloba Oral Drops, 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:

<table>
<thead>
<tr>
<th>Very common:</th>
<th>Common:</th>
</tr>
</thead>
<tbody>
<tr>
<td>more than 1 out of 10 treated</td>
<td>more than 1 out of 100 treated</td>
</tr>
</tbody>
</table>
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 as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.

5.2 Pharmacokinetic properties
Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.

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
No special requirements.

7 MARKETING AUTHORITY HOLDER
Dr. Willmar Schwabe GmbH & Co. KG
Willmar-Schwabe-Str. 4
D-76227 Karlsruhe
Germany

Distributed in the UK by:

Schwabe Pharma (UK) Limited
Alexander House
Mere Park
Dedmere Road
Marlow
Buckinghamshire
SL7 1PD

8 MARKETING AUTHORITY NUMBER(S)
THR 05332/0003

9 DATE OF FIRST AUTHORIZATION/RENEWAL OF THE AUTHORISATION
26/03/2008
10 DATE OF REVISION OF THE TEXT
23/05/2008
6: Product description

This product is a traditional herbal medicinal product containing *Pelargonium sidoides* root extract. 10g (=9.75mL) of oral solution contain 8g extract from the roots of *Pelargonium sidoides* DC (1:8-10) (EPs® 7630), extraction solvent 11% ethanol (v/v).

This product also contains the following ingredients:
- Glycerol 95%
- Ethanol

Each pack contains 20, 50 or 100mL oral solution.

Registration holder and manufacturer of this product:
Dr Willmar Schwabe GmbH & Co. KG
Willmar-Schwabe-Str. 4
76227 Karlsruhe
Germany

Distributor of this product in the UK:
Schwabe Pharma (UK) Ltd
Alexander House, Mere Park,
Dedmaston Road,
Marlow, Bucks
SL7 1PD

Traditional herbal registration number: THR 05332/0003

If you would like further information about this product, please contact:
Schwabe Pharma (UK) Ltd
Alexander House, Mere Park,
Dedmaston Road,
Marlow, Bucks, SL7 1PD
Telephone: 01628 488487
Email: info@schwabepharma.co.uk

This leaflet was prepared in April 2008

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**Patient Information Leaflet**

**Kaloba® oral drops, solution**

*Pelargonium sidoides* root extract 8g per 10g

Please read this leaflet carefully before you start taking this oral solution. It contains some important information about Kaloba.

Keep this leaflet with the oral solution. You may want to read it again or show it to your doctor, pharmacist or healthcare practitioner.

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**What is this leaflet**

1: What this product is and what it is used for ..................................... page 1
2: Before you take this product ............................................................... page 1-2
3: How to take this product ................................................................. page 2
4: Side-effects ....................................................................................... page 3
5: After taking this product ................................................................. page 3
6: Product description ........................................................................ page 4

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**1: What this product is and what it is used for**

This product is a traditional herbal medicinal product containing *Pelargonium sidoides* DC root extract. 10g (=9.75mL) of oral solution contain 8g of the liquid extract.

Kaloba is a 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.

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**2: Before you take this product**

DO NOT TAKE this product if you are:
- allergic to any of the ingredients (see section 6)
- suffer from severe liver or kidney disease
- pregnant or breast-feeding

If you suffer from an increased tendency to bleeding and/or take anti-coagulating drugs such as warfarin, there is a theoretical risk that taking this product may increase the risk of bleeding.

This product is not suitable for children under the age of 6 years.
Kaloba oral solution contains 12 vol% ethanol (alcohol).
This corresponds to:
- 180 mg alcohol equivalent to 3.5 ml beer or 1.5 ml wine per adult's single dose (30 drops)
- 120 mg alcohol equivalent to 2.4 ml beer or 1.8 ml wine per children's single dose (20 drops)
This is harmful for those suffering from alcoholism. The alcohol content should be taken into consideration when treating children and high-risk groups such as patients with liver disease or epilepsy.

3: How to take this product

| Adults and children over 12 years | Take 30 drops three times daily. |
| Children aged 6-12 years | Take 20 drops three times daily. |
| The correct dosage can be taken straight from a spoon or mixed with half a glass of water. The entire contents of the glass should be drunk straightaway. Take one dose in the morning, midday and evening. |

After the relief of symptoms, continue treatment for a further 2-3 days to prevent a relapse. However, treatment should not exceed two weeks.

Do not exceed the stated dose.

4: Side-effects

Like all medicines, this product can have side-effects, although not everybody gets them. They are listed below.

| Uncommon side-effects (affecting more than 1 in 1,000 but fewer than 1 in 100 people) |
| Gastro-intestinal complaints such as stomach pain, heartburn, nausea or diarrhoea. |

| Rare side-effects (affecting more than 1 in 10,000 but fewer than 1 in 1000 people) |
| Hypersensitivity reactions, e.g. skin rash, itching of the skin and mucous membranes |

Such reactions may occur when this product is first taken.

| Very rare side-effects (affecting 1 or fewer in 10,000 people) |
| Serious hypersensitivity reactions with swelling of the face, breathlessness and drop in blood pressure |

Single cases
Signs indicating changes in liver function have been reported after taking Kaloba; however, the causal relationship between these effects and the use of the product has not been demonstrated.

5: After taking this product

Consult a doctor immediately if your 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.

Do not use this product after the expiry date. Return any out-of-date product to your pharmacist who will dispose of it for you. The expiry date is printed on the box and also on the bottle label.

Store the product in a cool dry place. Do not store the product in a place where the temperature goes above 30°C.

Keep the product out of the reach and sight of children.
LABELLING

Bottle label:

Kaloba® oral drops 20ml

10g (=9.75ml) oral solution contain 8g extract from Pelargonium root (*Pelargonium sidoides* DC) (1:8-10) (Epstein® 7630). Extraction solvent: 11% ethanol (v/v).

A traditional herbal medicinal product used to relieve the symptoms of upper respiratory tract infections such as the common cold, based on traditional use only.

Read the patient information leaflet before use

Contains 12% (v/v) alcohol

Can be stored for three months after opening

Do not store above 30°C

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

UK distributor: Schwabe Pharma (UK) Ltd, Marlow, Bucks, SL7 1PD  Tel: 01628 488487

Kaloba® oral drops 50ml

10g (=9.75ml) oral solution contain 8g extract from Pelargonium root (*Pelargonium sidoides* DC) (1:8-10) (Epstein® 7630). Extraction solvent: 11% ethanol (v/v).

A traditional herbal medicinal product used to relieve the symptoms of upper respiratory tract infections such as the common cold, based on traditional use only.

Read the patient information leaflet before use

Contains 12% (v/v) alcohol

Can be stored for three months after opening

Do not store above 30°C

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

UK distributor: Schwabe Pharma (UK) Ltd, Marlow, Bucks, SL7 1PD  Tel: 01628 488487
Please read the enclosed patient information leaflet before taking this solution. Keep out of sight and reach of children.

Expiry date: see base
Do not store above 25°C
Store in original packaging
Manufactured in Germany

THR 05332/0003

S

Wiltmar Schwabe GmbH & Co. KG
Karlsruhe, Germany

UK distributors:
Schwabe Pharma (UK) Ltd
Mastonow, Bicks, SL7 1PD
Telephone: 01628 496487

NEW

Kaloba

Pelargonium sidoides root extract

A traditional herbal medicinal product used to relieve the symptoms of upper respiratory tract infections such as the common cold, based on traditional use only

Kaloba
Oral drops
50ml

Dr Willmar Schwabe GmbH & Co. KG
Wiltmar-Schwabe-Str. 4
D-76227 Karlsruhe
Germany

Active ingredient: 1g (± 0.75mg) of oral solution contains (g extract from Pelargonium root (Pelargonium sidoides) root extract CO2 (4-10g), 70% (v/v) ethanol) (v/v).

Dosage: Adults and children over 12 years: Take 10 drops three times daily. Children 0-12 years: Take 5 drops three times daily. The correct dosage can be taken directly from a spoon or mixed with a half a glass of water. The entire contents of the glass should be drunk straightway.

Warning: Do not exceed the stated dose. Do not use if you:
- are allergic to any of the ingredients
- suffer from severe hepatic and renal diseases
- you are pregnant or breast-feeding

If you suffer from an increased tendency to bleeding and/or take anti-coagulating drugs such as warfarin, there is a theoretical risk that taking this product may increase the risk of bleeding.

Not suitable for children under 6 years.

Contains 12% (v/v) alcohol.

*Proprietary extract of Dr Willmar Schwabe