5: How to store this product

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 Return any out-of-date product to your pharmacist who will dispose of it for you.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 the blister pack.

Store the product in a cool dry place.

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

6: Further information

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

This product also contains the following ingredients:

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 E 172, iron oxide red E 172, titanium dioxide E 171, talc, simeticone, methylcellulose, sorbic acid.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this product. Each film-coated tablet contains 20mg of lactose.

Each pack contains 16, 21 or 30 film-coated tablets. Not all pack sizes may be marketed.

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, Dedmere Road, Marlow, Bucks SL7 1FX



Traditional herbal registration number: THR 05332/0005

If you would like further information about this product, please contact: Schwabe Pharma (UK) Ltd Alexander House, Mere Park, Dedmere Road, , Marlow, Bucks, SL7 1FX Telephone: 01628 401980 Email: info@kaloba.co.uk

This leaflet was revised 01/2015

EPs® 7630 is a proprietary extract of Dr Willmar Schwabe GmbH & Co. KG

Patient Information Leaflet

Kaloba[®] Pelargonium Cough & Cold Relief tablets



Pelargonium sidoides root extract 20mg

Please read this leaflet carefully before you start taking these tablets.

It contains some important information about Kaloba Pelargonium Cough and Cold Relief.

Keep this leaflet with the tablets.

You may want to read it again or show it to your doctor, pharmacist or qualified healthcare practitioner.

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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. Each film-coated tablet of this product contains 20 mg of a dry extract from the roots of *Pelargonium sidoides* DC.

Kaloba Pelargonium Cough & Cold Relief 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)
- are lactose-intolerant (react badly to lactose or milk)
- suffer from severe liver disease
- are pregnant or breast-feeding

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

3: How to take this product

For oral use only.

Adults and children over 12 years

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

Swallow the tablet whole with some water. Do not chew the tablet.

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.

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

If you take too much of this product (overdose)

If you take more than the recommended dose, speak to your doctor, pharmacist or qualified healthcare practitioner and take this leaflet with you.

If you forget to take this product

Do not take twice the dose, but continue to take your usual dose at the usual time.

If you have any questions, or are unsure about anything, please ask your doctor, pharmacist or qualified healthcare practitioner.

4: Possible 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, vomiting, difficulty swallowing (dysphagia) or diarrhoea.

Rare side-effects (affecting more than 1 in 10,000 but fewer than 1 in 1000 people)

- mild bleeding from the gums or nose
- hypersensitivity reactions, e.g.

skin rash nettle rash itching of the skin and mucous membranes

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

Liver problems including hepatitis have been reported when taking this product. However, a causal relationship has not been established. The frequency is not known.

After taking this product

Consult a doctor immediately if your condition worsens, or 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.

Liver problems including hepatitis have been reported when taking this product. However, a causal relationship has not been established. The frequency is not known. If you become unwell (yellowing eyes/skin, nausea, vomiting, dark urine, abdominal pain, unusual tiredness, loss of appetite), stop taking immediately and seek medical advice.

Tell your doctor or pharmacist if any of the above side-effects becomes serious or if you notice any other side-effects not listed above.

Reporting of side-effects

If you get any side-effects, talk to your doctor, pharmacist or nurse. This includes any possible side-effects not listed in this leaflet. You can also report side-effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side-effects you can help provide more information on the safety of this medicine.