# Lane’s Red Sage Catarrh Remedy

**THR 15670/0024**

**UKPAR**

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LANE’S RED SAGE CATARRH REMEDY

THR 15670/0024

LAY SUMMARY

The Medicines and Healthcare Products Regulatory Agency (MHRA) granted Rickard Lane’s and W. H. Box Ltd a Traditional Herbal Registration Certificate for the traditional herbal medicinal product Lane’s Red Sage Catarrh Remedy (Traditional Herbal Registration number: THR 15670/0024) on 6 February 2013. Lane’s Red Sage Catarrh Remedy is available without prescription and can be bought from pharmacies and other outlets.

Lane’s Red Sage Catarrh Remedy is a traditional herbal medicinal product used to relieve the symptoms of colds, nasal congestion and sinusitis, and to relieve a chesty mucus cough, based on traditional use only.

The active ingredients in Lane’s Red Sage Catarrh Remedy are Red Sage (*Salvia officinalis* L.) leaf and Liquorice (*Glycyrrhiza glabra* L.) root. This registration is based exclusively upon evidence of the use of Red Sage leaf and Liquorice root as traditional herbal medicines 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.
LANE’S RED SAGE CATARRH REMEDY

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SCIENTIFIC DISCUSSION

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INTRODUCTION

The MHRA granted a Traditional Herbal Registration Certificate for the traditional herbal medicinal product Lane’s Red Sage Catarrh Remedy (THR 15670/0024) to Rickard Lane’s and W. H. Box Ltd on 6 February 2013. This product is on the general sales list (GSL).

A product licence of right (PLR) was originally granted to Joyce M Rickard for this product. The PLR was reviewed and a product licence (PL 04744/5911R) was granted to Joyce M Rickard on 12 March 1990. The product licence was transferred to Rickard Lane’s and W. H. Box Ltd on 6 December 1996 (PL 15670/0004). Rickard Lane’s and W. H. Box Ltd cancelled PL 15670/0004 on 6 February 2013, following the grant of the Traditional Herbal Registration Certificate.

This THR application was made under Article 16.c of Directive 2001/83 EC in accordance with arrangements to transfer certain herbal products with a Marketing Authorisation to a THR (according to MHRA Guidance dated January 2009). The application falls within the simplified THR application Category A, as no significant changes have been made to the formulation of the product. No new data were submitted, nor was it necessary for this application, as the data are essentially identical to those of the existing product.
**PHARMACEUTICAL ASSESSMENT**

**HERBAL SUBSTANCE: RED SAGE LEAF**

*Scientific name of the plant:* *Salvia officinalis* L.

*Plant family:* Lamiaceae

The herbal substance is acceptable.

**HERBAL PREPARATION: RED SAGE LEAF LIQUID EXTRACT**

*Extraction solvent:* Ethanol 21% v/v

The herbal preparation specification is in line with that applied to the herbal preparation used in the already licensed product. It is, therefore, acceptable.

**HERBAL SUBSTANCE: LIQUORICE ROOT**

*Scientific name of the plant:* *Glycyrrhiza glabra* L.

*Plant family:* Fabaceae

The herbal substance is acceptable.

**HERBAL PREPARATION: LIQUORICE ROOT LIQUID EXTRACT**

*Extraction solvent:* Ethanol 18% v/v

The herbal preparation specification is in line with that applied to the herbal preparation used in the already licensed product. It is, therefore, acceptable.

**HERBAL PRODUCT: LANE’S RED SAGE CATARRH REMEDY**

**Description and Composition of the Herbal Product**

Lane’s Red Sage Catarrh Remedy is a dark brown, slightly viscous oral liquid. Each 5 ml of oral liquid contains 0.2 ml of Red sage leaf liquid extract and 0.55 ml of Liquorice root liquid extract and the pharmaceutical excipients garlic oil (*Allium sativum* L.), tragacanth, juniper berry oil, pumilio pine oil, menthol, sucrose (syrup), golden syrup, ethanol, water and talc. The formulation is identical to that of the already licensed product. It is, therefore, acceptable.

**Manufacture**

The manufacturing process is in line with that of the already licensed product and is satisfactory.

**Finished Product Specification**

The finished product specification is in line with that of the already licensed product and is satisfactory.
**Container Closure System**
The oral liquid is stored in an amber glass bottle with a hard polypropylene screw-cap. Pack sizes of 100 ml, 150 ml and 300 ml have been authorised, although not all pack sizes may be marketed. This type of packaging has been used to store the already licensed product and is satisfactory.

**Stability**
The product has a shelf-life of 3 years when the storage precaution ‘Store in the original container’ is applied. This is in line with the already licensed product and is appropriate.

**Summary of Product Characteristics, product labels and Patient Information Leaflet**
All product literature is in line with that of the already licensed product, with some details amended in line with other products registered under the THR scheme.

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 CONCLUSION**
It is recommended that a Traditional Herbal Registration can be granted.
PRECLINICAL ASSESSMENT

INTRODUCTION
No new preclinical data have been supplied with this application and none is required for an application of this type.

Assurance has been given that the results of genotoxicity testing will be provided by the renewal date of the Traditional Herbal Registration.

PRODUCT LITERATURE
All product literature is satisfactory from a preclinical point of view.

ASSESSOR’S OVERALL CONCLUSION
It is recommended that a Traditional Herbal Registration can be granted.
CLINICAL ASSESSMENT

INTRODUCTION
The clinical particulars for Lane’s Red Sage Catarrh Remedy are identical to those for the already licensed product. This is satisfactory.

PRODUCT LITERATURE
All product literature is medically satisfactory.

ASSESSOR’S OVERALL CONCLUSION
It is recommended that a Traditional Herbal Registration can be granted.
OVERALL CONCLUSION AND BENEFIT-RISK ASSESSMENT

QUALITY
Lane’s Red Sage Catarrh Remedy is identical to an already licensed product. It is, therefore, pharmaceutically satisfactory.

PRECLINICAL
No new preclinical data were submitted and none are required for an application of this type. The results of genotoxicity testing will be provided before the THR is renewed.

EFFICACY
No clinical efficacy data are required for registration of Traditional Herbal Medicinal Products.

SAFETY
No new or unexpected safety concerns arose from this application.

BENEFIT-RISK ASSESSMENT
The quality of the product is acceptable and no new preclinical or clinical safety concerns have been identified. The benefit: risk balance is acceptable and a THR should be granted.
## STEPS TAKEN FOR ASSESSMENT

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<td>The MHRA received the Traditional Herbal Registration application on 26 October 2012</td>
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<td>Following standard checks and communication with the applicant the MHRA considered the application valid on 30 October 2012</td>
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<td>Following assessment of the application the MHRA requested further information relating to the dossier on 10 January 2013</td>
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<td>The applicant responded to the MHRA’s requests, providing further information on the dossier on 5 February 2013</td>
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<td>A THR was granted on 6 February 2013</td>
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SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT
Lane’s Red Sage Catarrh Remedy

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
Each 5 ml of oral liquid contains:-

0.2 ml of extract (as liquid extract) from Red Sage leaf (Salvia officinalis L.)
(equivalent to 200mg Red Sage)
Extraction Solvent: Ethanol 21% v/v

0.55 ml of extract (as liquid extract) from Liquorice root (Glycyrrhiza glabra L.)
DER (equivalent to 550 mg Liquorice root)
Extraction Solvent: Ethanol 18% v/v
5 ml of oral liquid contains approximately 0.4 ml of ethanol and 1.15mg of
sucrose. (See section 4.4 ‘Special warnings and precautions for use’.)
For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM
Oral liquid.
Dark brown slightly viscous liquid.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications
A traditional herbal medicinal product used to relieve the symptoms of colds,
nasal congestion and sinusitis, and to relieve a chesty mucus cough, based on
traditional use only.

4.2 Posology and method of administration
For oral use.
Adults and the elderly: Take one 5 ml teaspoonful three or four times a day,
and during the night sipped slowly.

Maximum recommended daily dose: 20 ml (4 doses)

Adolescents and children over 12 years old: Take one 5 ml teaspoonful three
times a day (six hours apart).

Maximum recommended daily dose : 15 ml (3 doses)

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

If the symptoms worsen or persist for more than 7 days during the use of this
medicinal product, a doctor or a qualified health care practitioner should be consulted.

4.3 Contraindications
Hypersensitivity to the active ingredients or to any of the excipients.

4.4 Special warnings and precautions for use
Do not exceed the stated dose.
The use is not recommended in children under 12 years of age due to the lack of adequate data.

Patients taking liquorice medication should not take other liquorice containing products as serious adverse events may occur such as water retention, hypokalemia, hypertension, cardiac rhythm disorders.

Liquorice is not recommended to be used in patients affected by hypertension, kidney diseases, liver or cardiovascular disorders or hypokalemia, as they are more sensitive to adverse effects of liquorice.

If dyspnoea, fever or purulent sputum, occurs, a doctor or a qualified healthcare practitioner should be consulted.

If symptoms worsen or persist for more than 7 days during the use of this medicinal product, a doctor or qualified health care practitioner should be consulted.

Patients with rare hereditary problems of fructose intolerance, glucosegalactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

This medicinal product contains approximately 18.1 % v/v ethanol (alcohol), i.e. up to 905 mg per dose, equivalent to 18.7 ml beer, 7.54 ml wine per dose. Harmful for those suffering from alcoholism. To be taken into account in pregnant or breast-feeding women, 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
No studies have been carried out to determine if drug interactions occur with this product.
The intake of Sage leaf preparations might influence the effect of medicinal products acting via GABA receptor (e.g. barbiturates, benzodiazepines), even if not seen clinically. Therefore the concomitant use with such medicinal products is not recommended.

Liquorice root may counteract antihypertensive action of prescribed medications.
Not to be used concomitantly with diuretics, cardiac glycosides, corticosteroids, stimulant laxatives or other medications which may aggravate electrolyte imbalance.
Contains alcohol and should be avoided in patients taking other medicines known to interact with alcohol (e.g. metronizadole).

4.6 **Fertility, pregnancy and lactation**  
Studies in animals have shown reproductive toxicity with liquorice (See Section 5.3 Preclinical safety data)  
The safety of this product during pregnancy and lactation has not been established. In the absence of sufficient data the use of this product during pregnancy and lactation is not recommended.  
Studies on the effect of this product on fertility have not been performed.

4.7 **Effects on ability to drive and use machines**  
Sage leaf may impair ability to drive and use machines. Affected patients should not drive or operate machines.  
This product contains alcohol and therefore may impair ability to drive or operate machines. If affected do not drive or operate machines (See Section 4.4 ‘Special warnings and precautions for use’.)

4.8 **Undesirable effects**  
None known.  
If adverse reactions occur, a doctor or qualified health care practitioner should be consulted.

4.9 **Overdose**  
No cases have been reported with this product.

Overdose has been reported with a sense of heat, tachycardia, vertigo and epileptic form convulsions (seizures) after intake corresponding to more than 15 g of sage leaves (equivalent to 2.5 x 150ml bottles of this product).

Cases of overdose have been reported with prolonged use of liquorice (more than 4 weeks) and/or intake of high amounts of liquorice with symptoms such as water retention, hypokalaemia, hypertension, cardiac rhythm disorders, hypertensive encephalopathy.

Overdose of this products may result in alcohol intoxication; the amount of alcohol in a full bottle (18.1g in 100 ml, 27.15g in 150 ml: equivalent to 0.6 or 0.9 large glasses of wine respectively or 1.45 or 2.17 glasses of beer, respectively) may result in intoxication and should be treated accordingly.

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**

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

**Liquorice**

A study has shown that 18β-glycyrrhetinic acid a constituent of liquorice, crosses through the placental barrier and can be detected in the rat foetuses. Following feeding of dams with 100mg 18β-glycyrrhetinic acd/kg/day commencing on the 13th day of gestation, on the 17th, 19th and 21st days of gestation the maternal plasma 18β-glycyrrhetinic acid concentrations were approximately 100µg/ml, whereas the foetal concentrations were 5, 18 and 32µg/ml respectively.

In development toxicity studies, glycyrrhizin (ammonium salt) exhibited some embryotoxicity to the developing rat foetus but the foetal effects were considered as minor. These effects were shown at the dose of 100 and 250 mg/kg of ammonium glycyrrhizin from 7th to 20th day of pregnancy (soft-tissue abnormalities, mostly renal and external haemorrhages) and at the dose of 1000 mg/kg of 18β-glycyrrhetinic acid from the 13th day of gestation (significant reduction in lamellar body content of lungs and reduced number alveolar body and surfactant clusters, but no apparent increase in malformation of foetal death rate).

Another study suggested that 100 mg/kg of liquorice extract repeated for 7 days may also aggravate body weight loss and malformations of foetuses, induced by intrauterine exposure to cyclophosphamide.

6 **PHARMACEUTICAL PARTICULARS**

6.1 **List of excipients**

Garlic oil (*Allium sativum* L.)

Tragacanth

Juniper Berry Oil

Pumilio Pine Oil

Menthol

Sucrose (syrup)

Golden syrup

Ethanol

Water

Talc

6.2 **Incompatibilities**

Not applicable.

6.3 **Shelf life**

Three years.

6.4 **Special precautions for storage**

This medicinal product does not require any special storage conditions. Store in the original container.
6.5 Nature and contents of container
Amber glass bottle with hard polypropylene screw-cap: 100 ml, 150 ml and 300 ml.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal
There are no special precautions for disposal.

7 MARKETING AUTHORITY HONDER
Rickard Lane’s and W. H. Box Ltd
24 Tennant Street
Edinburgh
EH6 5ND

8 MARKETING AUTHORITY NUMBER(S)
THR 15670/0024

9 DATE OF FIRST AUTHORIZATION/RENEWAL OF THE AUTHORIZATION
06/02/2013

10 DATE OF REVISION OF THE TEXT
06/02/2013
5. HOW TO STORE THIS PRODUCT
Do not use this product after the expiry date. The expiry date is printed on the label and on the bottom of the carton.
This product does not require any special storage or disposal.
Keep this product out of the reach and sight of children.

6. FURTHER INFORMATION
Each 5 ml of oral liquid contains:
0.2 ml liquid (as liquid extract) from Red Sage leaf (Salvia officinalis L.) (1)
(equivalent to 200 mg Red Sage leaf).
Extraction solvent: Ethanol 21% v/v.
0.55 ml liquid (as liquid extract) from Liquorice root (Glycyrrhiza glabra L.) (1)
(equivalent to 550 mg Liquorice root).
Extraction solvent: Ethanol 18% v/v.

This product also contains:
Traganth, juniper berry oil, garlic oil, fumitory pine oil, menthol, sucrose syrup, golden syrup, ethanol, water and talc.

This product is a dark brown syrupy liquid. It comes in a 100 ml, 150 ml or 300 ml glass bottle with a child-resistant safety cap. Not all sizes may be marketed.

Traditional Herbal Registration holder:
Rickard Lane’s and W. H. Box Ltd,
24 Tennant Street, Edinburgh EH6 5ND

Product manufacturer:
Potters Ltd, 1 Botanic Court, Martland Park, Wigan WN5 0JZ

Traditional Herbal Registration number: THR 15670/0024

Leaflet revised 29/01/2013 RIC14LEA1

What is Red Sage?
Red Sage, also known as Garden Sage, is a scented, woody, plant native to Europe.

What is Liquorice?
The liquorice plant is a legume (related to beans and peas) and the root has a sweet flavour.

Further Enquiries
A copy of this leaflet in large format print is available.
If you would like more information about this product please contact:
Napiers the Herbalists
24 Tennant Street, Edinburgh EH6 5ND
Telephone: 0845 002 1860

PATIENT INFORMATION LEAFLET
LANE’S RED SAGE CATARRH REMEDY
with extracts of Sage leaf & Liquorice root
Please read this leaflet carefully before you start taking this product.
It contains important information for you about this product that may affect you.
Keep this leaflet. You may wish to read it again.
You must contact a doctor or healthcare practitioner if your symptoms do not improve after 7 days.
If any side effects become serious, or if you notice side effects not listed in here, please tell your doctor or pharmacist.

What is in this leaflet?
1. What this product is and what it is used for.
2. Before you take this product
3. How to take this product
4. Possible side effects
5. How to store this product
6. Further information

NAPIERS
EDINBURGH 1860
HERB & PLANT REMEDIES
1. WHAT THIS PRODUCT IS AND WHAT IT IS USED FOR
Lane’s Red Sage Catarrh Remedy is a traditional herbal medicinal product containing extracts of Sage leaf and Liquorice root. For full details see Section 6.
Lane’s Red Sage Catarrh Remedy is a traditional herbal medicinal product used to relieve the symptoms of colds, nasal congestion and sinusitis, and to relieve a chesty, mucus cough, based on traditional use only.

2. BEFORE YOU TAKE THIS PRODUCT
Do not take this product if you:
- are under 12 years old
- are pregnant or breastfeeding
- are allergic to any of the ingredients
- are taking other liquorice products
- have kidney or liver disease, or heart problems
- have low potassium levels in your blood (hypokalemia)
- have high blood pressure

Do not take this product if you are taking medicines:
- to control high blood pressure
- that are a tranquilliser medicine e.g. benzodiazepine, barbiturates
- diuretics
- cardiac glycosides e.g. digoxin
- corticosteroids e.g. prednisone
- laxatives
- that might affect electrolyte imbalance
- that are known to interact with alcohol e.g. metronidazole

Important information about some of the ingredients in this medicine
This product contains 18.1% v/v ethanol (alcohol), i.e. up to 905 mg per dose, equivalent to 18.7 ml beer, 7.54 ml wine per dose. Harmful for people suffering from alcoholism or liver disease. If you are in a high risk group (patients with liver disease or epilepsy) you should consider the alcohol content before taking this product.
This product contains 1.15 mg of sucrose per 5 ml dose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Driving and using machines
This product contains alcohol and therefore may impair ability to drive or operate machines. If affected do not drive or operate machines.

3. HOW TO TAKE THIS PRODUCT
For oral use only.
Adults and the elderly:
One 5 ml teaspoonful three to four times a day, and during the night sipped slowly
Maximum daily dose: 20 ml (4 doses).
Adolescents and children over 12 years of age:
Take one 5 ml teaspoonful three times a day (six hours apart).
Maximum daily dose: 15 ml (3 doses).
Do not exceed the stated dose.
If your symptoms worsen, if you experience shortness of breath, fever or blood in your saliva, or if symptoms persist for more than 7 days speak to your doctor, pharmacist or qualified healthcare practitioner.

If you take too much (overdose).
If you take more than the recommended dose, speak to a doctor, pharmacist or qualified healthcare practitioner and take this leaflet with you.

Overdose of this product may result in alcohol intoxication and should be treated accordingly. (See Section 2.)

If you forget to take this product
Continue to take your usual dose at the usual time. Do not take a double dose. It does not matter if you miss a dose.
If you have any questions, or are unsure of anything, please speak to your doctor, pharmacist or healthcare practitioner.

4. POSSIBLE SIDE EFFECTS
No side effects have been reported with this product. If you notice any side effects please tell your doctor, pharmacist or qualified healthcare practitioner.

Making medicines safer
You can help to make medicines safer by reporting any side-effects to the Yellow Card Scheme at www.yellowcard.gov.uk. Alternatively you can get a paper Yellow Card form from your doctor’s surgery or a pharmacy, or call freephone 0808 100 3352 (available 10am-2pm Monday to Friday).
Label: