Public Summary

Summary for ARTG Entry:	315176 Ki Sore Throat Spray
ARTG entry for	Medicine Listed
Sponsor	Martin & Pleasance Pty Ltd
Postal Address	PO Box 2007, SOUTH MELBOURNE, VIC, 3205 Australia
ARTG Start Date	7/03/2019
Product Category	Medicine
Status	Active
Approval Area	Listed Medicines

Conditions

Colouring agents used in listed medicine for ingestion, other than those listed for export only under section 25 of the Act, shall be only those included in the list of 'Colourings permitted in medicines for oral use'.

The sponsor shall keep records relating to this listed medicine as are necessary to: (a) Expedite recall if necessary of any batch of the listed medicine, (b) Identify the manufacturer(s) of each batch of the listed medicine. Where any part of or step in manufacture in Australia of the listed medicine is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relation to such manufacture shall be kept.

The sponsor shall retain records of the distribution of the listed medicine for a period of five years and shall provide the records or copies of the records to the Complementary Medicines Branch, Therapeutic Goods Administration, upon request.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

Where a listed medicine is distributed overseas as well as in Australia, product recall or any other regulatory action taken in relation to the medicine outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia, must be notified to the National Manager Therapeutic Goods Administration, immediately the action or information is known to the sponsor.

Products

1 . Ki Sore Throat Spray

Product Type Single Medicine Product **Effective Date** 22/01/2020

Permitted Indications

Traditionally used in Chinese medicine to dispel/expel/extinguish/disperse/clear wind-heat

Traditionally used in Western herbal medicine to maintain/support immune system health

Traditionally used in Western herbal medicine to helps enhance/improve/promote immune system function

Traditionally used in Chinese medicine to decrease/reduce/relieve symptoms of common cold

Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of common cold

Traditionally used in European herbal medicine to decrease/reduce/relieve symptoms of common cold

Traditionally used in Chinese medicine to relieve symptoms of sore throat/pharyngitis

Linked indication - Decrease/reduce/relieve throat mucous membrane irritation/inflammation
Linked indication - Decrease/reduce/relieve mild throat inflammation

Indication Requirements

Label statement: If symptoms persist, talk to your health professional.

Label statement: Adults only, OR Not to be used in children under 2 years of age without medical advice (or words to that effect).

Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.

If TCM terminology is used on medicine label, label statement: Talk to a TCM practitioner/health professional if you are unsure if this medicine is right for you.

Product presentation must not imply or refer to serious immunological diseases.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

If symptoms persist consult your healthcare practitioner (or words to that effect).

Contains ethanol or contains alcohol.

Contains sorbates' (or word to this effect) if medicine contains two or more sorbate sources OR 'Contains [insert the approved name of sorbate source used]' (or words to this effect) if medicine contains one sorbate source.

(If medicine contains one sugar) contains [insert name of sugar] OR (If medicine contains two or more sugars) Contains sugars [or words to that effect].

Not suitable for infants under the age of twelve months (or words to that effect).

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule

Components

1 . Formulation 1

Dosage Form	Spray
Route of Administration	Oral
Visual Identification	

Active Ingredients

Clove Bud Oil	**2.5 mg/mL**
Echinacea purpurea herb Juice concentrate	**13.9 mg/mL**
Equivalent: Echinacea purpurea (Dry)	626 mg/mL
Lonicera japonica flower Extract dry concentrate	**62.5 mg/mL**
Equivalent: Lonicera japonica (Dry)	1.25 g/mL

Other Ingredients (Excipients)

ethanol
glycerol
Honey
maltodextrin
potassium sorbate
purified water
xylitol