Public Summary

Summary for ARTG Entry:	317277 Herbal Head Cold
ARTG entry for	Medicine Listed
Sponsor	Lyndelen Pty Ltd T/A The Herbal Extract Co of Australia
Postal Address	PO Box 107, PANANIA, NSW, 2213 Australia
ARTG Start Date	7/05/2019
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 . Herbal Head Cold

Product Type Single Medicine Product **Effective Date** 7/05/2019

Permitted Indications

Antioxidant/Reduce free radicals formed in the body

Helps enhance/promote general health and wellbeing

Maintain/support general health and wellbeing

Maintain/support immune system health

Enhance/improve/promote immune defence/immunity

Helps enhance/improve/promote immune system function

Maintain/support immune system to fight illness

Helps stimulate a healthy immune system response

Decrease/reduce/relieve symptoms of common colds and flu

- Linked indication - Sudorific/diaphoretic/enhance/promote sweating/perspiration
- Linked indication - Helps reduce occurrence of common colds
- Linked indication - Decrease/reduce/relieve common cold duration
- Linked indication - Decrease/reduce/relieve throat mucous membrane irritation/inflammation
- Linked indication - Decrease/reduce/relieve mild upper respiratory tract congestion
- Linked indication - Relieve symptoms of mild upper respiratory tract infections
- Linked indication - Helps reduce occurrence of symptoms of upper respiratory tract infections
- Linked indication - Helps decrease/reduce/relieve the severity of symptoms of common colds and flu

Decrease/reduce/relieve symptoms of head cold

Decrease/reduce/relieve the severity of symptoms of mild upper respiratory tract infections

Indication Requirements

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

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

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).

Respiratory tract infections must be qualified by 'mild'.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Contains ethanol or contains alcohol.

Use in children under 3 years is not recommended.

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule

Components

1 . Formulation 1

Dosage Form	Oral Liquid
Route of Administration	Oral
Visual Identification	

Active Ingredients

Achillea millefolium herb Extract liquid	**70 mg/mL**
Equivalent: Achillea millefolium (Dry)	70 mg/mL
Calendula officinalis flower Extract liquid	**42 mg/mL**
Equivalent: Calendula officinalis (Dry)	42 mg/mL
Cinnamomum verum stem bark outer Extract liquid	**21 mg/mL**
Equivalent: Cinnamomum verum (Dry)	21 mg/mL
Echinacea purpurea whole plant Extract liquid	**105 mg/mL**
Equivalent: Echinacea purpurea (Dry)	105 mg/mL
Euphrasia officinalis herb Extract liquid	**105 mg/mL**
Equivalent: Euphrasia officinalis (Dry)	105 mg/mL
Plantago lanceolata leaf Extract liquid	**84 mg/mL**
Equivalent: Plantago lanceolata (Dry)	84 mg/mL
Sambucus nigra flower Extract liquid	**210 mg/mL**
Equivalent: Sambucus nigra (Dry)	210 mg/mL
Tilia cordata flower Extract liquid	**70 mg/mL**
Equivalent: Tilia cordata (Dry)	70 mg/mL

Other Ingredients (Excipients)

Anise Oil

glycerol

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