Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	172086	LING NAM ULTRA BALM
ARTG entry for	Medicine Listed	
Sponsor	Shen Neng Herbal Medicines Group Pty Ltd	
Postal Address	1 Clarke Street, GUILDFORD, NSW, 2161 Australia	
ARTG Start Date	8/06/2010	
Product Category	Medicine	
Status	Active	
Approval Area	Listed Medicines	

Conditions

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 . LING NAM ULTRA BALM

Product Type Single Medicine Product **Effective Date** 9/01/2020

Permitted Indications

Traditionally used in Chinese medicine to decrease/reduce/relieve mild rheumatic aches and pains

Traditionally used in Chinese medicine to decrease/reduce/relieve mild joint pain/soreness

Traditionally used in Chinese medicine to decrease/reduce/relieve symptoms of motion/travel/sea sickness

Traditionally used in Chinese medicine to decrease/reduce/relieve muscle cramps

Traditionally used in Chinese medicine to helps decrease/reduce/relieve mild muscle spasms/twitches

Traditionally used in Chinese medicine to decrease/reduce/relieve muscle pain/ache/soreness

Traditionally used in Chinese medicine to decrease/reduce mental/cognitive fatigue

Decrease/reduce/relieve symptoms of common cold

Traditionally used in Chinese medicine to decrease/reduce/relieve symptoms of insect bite/sting

Indication Requirements

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

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

Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis. Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.

Product presentation must only refer to mild joint symptoms.

Product presentation must not imply or refer to mental illnesses, disorders or conditions.

Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.

Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.

Product presentation must only refer to mild rheumatic aches/pains.

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

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).

Avoid contact with eyes (or words to that effect).

If irritation develops, discontinue use.

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule

Components

1 . Formulation 1

Dosage Form	Ointment
Route of Administration	Topical
Visual Identification	

Active Ingredients

Eucalyptus Oil	**159 mg/g**
Peppermint Oil	**294.6 mg/g**
wintergreen oil	**220 mg/g**

Other Ingredients (Excipients)

camphor
hard paraffin
Thyme Oil
white soft paraffin
Wool fat

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