Public Summary

Summary for ARTG Entry: 291481 Zea Relief Kunzea Balm

ARTG entry for	Medicine Listed
Sponsor	Australian Kunzea Pty Ltd
Postal Address	209/87 Griffith Street, Coolangatta, QLD, 4225 Australia
ARTG Start Date	13/07/2017
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.

Preparations that contain, as their therapeutically active ingredient, Kunzea ambigua in topical products only, are subject to the following conditions: (i) Must include the label warning (EXTERN) - For external use only; and (ii) Must include the label warning (CHILD) - Keep out of reach of children (or words to that effect).

Products

1. Zea Relief Kunzea Balm

Product Type Single Medicine Product **Effective date** 13/07/2017

Permitted Indications

No Permitted Indications included on Record

Indication Requirements

No Indication Requirements included on Record

Standard Indications

May help enhance/improve/promote/increase joint mobility in mild arthritis

May assist in the management of eczema. [Warning S required]

Relief of muscular aches and pains. [Warning S required]

May assist in the management of dry skin.

May temporarily relieve joint inflammation/ swelling associated with mild arthritis

May temporarily relieve joint pain/aches associated with mild arthritis

Specific Indications

No Specific Indications included on Record

Warnings

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

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Jar/Can	Not recorded	Not recorded	Not recorded	Not recorded	Not recorded

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1. Formulation 1

Dosage Form	Cream
Route of Administration	Topical
Visual Identification	

Active Ingredients

Evening Primrose Oil	**75 mg/g**
Kunzea ambigua	**50 mg/g**
Rose Oil	**10 mg/g**