Public Summary

Summary for ARTG Entry:	360331	Kunzea Pain Relief Cream

ARTG entry for	Medicine Listed
Sponsor	Australian Kunzea Pty Ltd
Postal Address	209/87 Griffith Street, Coolangatta, QLD, 4225 Australia
ARTG Start Date	8/04/2021
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.

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 . Kunzea Pain Relief Cream

Product Type	Single Medicine Product	**Effective Date**	8/04/2021

Permitted Indications

Antioxidant/Reduce free radicals formed in the body
Helps reduce/decrease free radical damage to body cells
Relieve feelings of general malaise/general debility
Helps enhance/promote/increase vitality
Maintain/support vitality
Anti-inflammatory/relieve inflammation
Analgesic/Anodyne/relieve pain
Decrease/reduce/relieve mild rheumatic aches and pains
Decrease/reduce/relieve symptoms of mild arthritis/mild osteoarthritis
Decrease/reduce/relieve mild joint pain/soreness
Decrease/reduce/relieve symptoms of muscle injury/ailments
Aid/assist/helps in the management of muscle sprain/strain
Helps decrease/reduce/relieve symptoms of muscle sprain/strain
Decrease/reduce/relieve muscle pain/ache/soreness
Decrease/reduce/relieve mild nerve pain/neuralgia
Decrease/reduce/relieve symptoms of mild sciatica
Soothe skin
Soothe/relieve skin inflammation
Decrease/reduce/relieve skin irritation
Decrease/reduce skin sensitivity
Helps enhance/promote skin health
Maintain/support skin health
Maintain/support skin hydration

Indication Requirements

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

Product presentation must not imply or refer to chronic fatigue syndrome.
Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.
Product presentation must only refer to mild nerve pain/neuralgia.
Product presentation must only refer to mild joint symptoms.
Product presentation must only refer to mild rheumatic aches/pains.
Product presentation must not imply or refer to mental illnesses, disorders or conditions.
Product presentation must only refer to mild sciatica.

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).

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule

Components

1 . Formulation 1

Dosage Form	Cream
Route of Administration	Topical
Visual Identification	

Active Ingredients

Kunzea ambigua leaf Oil essential	**75 mg/g**
Lavender Oil	**5 mg/g**
mixed (low-alpha type) tocopherols concentrate	**10 mg/g**
Rosmarinus officinalis leaf Extract liquid concentrate	**5 mg/g**
Equivalent: Rosmarinus officinalis (Dry)	35.5 mg/g

Other Ingredients (Excipients)

benzyl alcohol
cetostearyl alcohol
Coconut Oil
dehydroacetic acid
glycerol
glyceryl caprylate
Macadamia nut oil
medium chain triglycerides
potassium cetyl phosphate
purified water
sorbitan olivate
Soya Oil
Theobroma Oil
Vitellaria paradoxa
xanthan gum

Public Summary