



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	372260	DUCANE KUNZEA OIL
ARTG entry for	Medicine Listed	
Sponsor	JJ Hood T/A Ducane Estate	
Postal Address	PO Box 155, BRIDPORT, TAS, 7262 Australia	
ARTG Start Date	5/08/2021	
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.

Products

1 . DUCANE KUNZEA OIL

Product Type	Single Medicine Product	Effective Date	5/08/2021
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Permitted Indications

- Decrease/reduce/relieve symptoms of mild arthritis/mild osteoarthritis
- Decrease/reduce/relieve muscle pain/ache/soreness
- Decrease/reduce/relieve symptoms of stress
- Decrease/reduce/relieve nervous tension/unrest
- Decrease/reduce/relieve symptoms of mild anxiety
- Helps decrease/reduce/relieve the severity of symptoms of common colds and flu
- Decrease/reduce/relieve symptoms of common colds and flu
- Decrease/reduce/relieve mild upper respiratory tract congestion
- Decrease/reduce/relieve the severity of symptoms of mild upper respiratory tract infections

Indication Requirements

- Respiratory tract infections must be qualified by 'mild'.
- Product presentation must not imply or refer to mental illnesses, disorders or conditions.
- 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.
- 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 joint symptoms.
- Product presentation must only refer to mild anxiety.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Keep out of reach of children (or words to that effect).

Additional Product information

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Container information					
Type	Material	Life Time	Temperature	Closure	Conditions
Bottle	Not recorded	Not recorded	Not recorded	Not recorded	Not recorded
Pack Size/Poison information					
Pack Size			Poison Schedule		
Components					
1 . Formulation 1					
Dosage Form	Liquid, multipurpose				
Route of Administration	Inhalation				
Visual Identification					
Active Ingredients					
Kunzea ambigua herb Oil essential				1 mL/mL	

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