



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	346209	Artemisia Plus
ARTG entry for	Medicine Listed	
Sponsor	Interclinical Laboratories Pty Ltd	
Postal Address	PO Box 6474, ALEXANDRIA, NSW, 2015 Australia	
ARTG Start Date	20/10/2020	
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.

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.

The warning statement 'Do not use if pregnant or likely to become pregnant' must be displayed on the medicine label.

Products

1 . Artemisia Plus

Product Type	Single Medicine Product	Effective Date	20/10/2020
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Permitted Indications

- Traditionally used in Chinese medicine to clear/expel/dissipate stomach-coldness
- Traditionally used in Chinese medicine to soothe/descend the arisen stomach-qi
- Traditionally used in Chinese medicine to warm and nourish/strengthen/tonify/enrich kidneys/kidney-yang
- Traditionally used in Western herbal medicine to maintain/support general health and wellbeing
- Traditionally used in Chinese medicine to maintain/support general health and wellbeing
- Traditionally used in Chinese medicine to antipyretic/febrifuge/relieve mild fever/reduce body temperature/body cooling
- Traditionally used in Chinese medicine to orexigenic/improve/promote healthy appetite
- Traditionally used in Western herbal medicine to maintain/support healthy appetite
- Traditionally used in Chinese medicine to decrease/reduce/relieve diarrhoea
- Traditionally used in Western herbal medicine to decrease/reduce/relieve colic (wind/gas pain)
- Traditionally used in Western herbal medicine to decrease/reduce/relieve flatulence/carminative
- Traditionally used in Western herbal medicine to maintain/support healthy digestive system function
- Traditionally used in Western herbal medicine to maintain/support healthy digestion
- Traditionally used in Chinese medicine to decrease/reduce/relieve abdominal pain/discomfort
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of indigestion/dyspepsia
- Traditionally used in Chinese medicine to decrease/reduce/relieve hiccups
- Traditionally used in Chinese medicine to antiemetic/Decrease/reduce/relieve vomiting
- Traditionally used in Western herbal medicine to antispasmodic/spasmolytic
- Traditionally used in Western herbal medicine to expectorant/clear respiratory tract mucous
- Traditionally used in Western herbal medicine to relieve symptoms of mild upper respiratory tract infections
- Traditionally used in Western herbal medicine to decrease/reduce/relieve mild bronchial cough
- Traditionally used in Western herbal medicine to decrease/reduce/relieve cough

Indication Requirements

- Product presentation must not imply or refer to eating disorders.
- Product presentation must not imply or refer to gastro oesophageal reflux disease.



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

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 musculoskeletal or neurological conditions.

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 only refer to mild bronchitis.

Product presentation must not imply or refer to disease in any body organ.

If TCM terminology is used on medicine label, label statement: Talk to a TCM practitioner/health professional if you are unsure if this medicine is right for you.

Label statement: Not to be used in children under 5 years.

Label statement: Seek medical advice if diarrhoea persists for more than: 6 hours in infants under 6 months, 12 hours in children under 3 years, 24 hours in children aged 3 to 6 years or 48 hours in adults and children over 6 years (or words to that effect).

Product presentation must not imply or refer to kidney disease.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Use in children under 12 years is not recommended.

Do not use if pregnant or likely to become pregnant (or words to that effect)

Do not use while breastfeeding.

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form	Capsule, hard
Route of Administration	Oral

Visual Identification

Active Ingredients

Artemisia annua leaf Extract dry concentrate	250 mg
Equivalent: Artemisia annua (Dry)	2.5 g
Artemisia vulgaris leaf Extract dry concentrate	25 mg
Equivalent: Artemisia vulgaris (Dry)	250 mg
Foeniculum vulgare seed Extract dry concentrate	80 mg
Equivalent: Foeniculum vulgare (Dry)	400 mg
Handroanthus impetiginosus stem bark Extract dry concentrate	40 mg
Equivalent: Handroanthus impetiginosus (Dry)	400 mg
ornithine monohydrochloride	64.1 mg
Equivalent: ornithine	50 mg
Syzygium aromaticum flower bud Extract dry concentrate	50 mg
Equivalent: Syzygium aromaticum (Dry)	500 mg
Thymus vulgaris leaf Extract dry concentrate	100 mg
Equivalent: Thymus vulgaris (Dry)	550 mg
Uncaria tomentosa twig bark Extract dry concentrate	40 mg
Equivalent: Uncaria tomentosa (Dry)	400 mg

Other Ingredients (Excipients)

Acacia
 colloidal anhydrous silica

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hypromellose
magnesium stearate
maltodextrin
microcrystalline cellulose
purified water
silicon dioxide

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