



Australian Government

Department of Health, Disability and Ageing
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	299587	Cold & Flu Strike
ARTG entry for	Medicine Listed	
Sponsor	Herbs of Gold Pty Ltd	
Postal Address	Suite 802 Level 8 1-5 Chalmers Crescent Mascot, Sydney, NSW, 2020 Australia	
ARTG Start Date	13/02/2018	
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.

Products

1 . Cold & Flu Strike

Product Type	Single Medicine Product	Effective Date	2/09/2025
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Permitted Indications

Antioxidant/Reduce free radicals formed in the body
Maintain/support general health and wellbeing
Traditionally used in Western herbal medicine to antipyretic/febrifuge/relieve mild fever/reduce body temperature/body cooling
Traditionally used in Ayurvedic medicine to antipyretic/febrifuge/relieve mild fever/reduce body temperature/body cooling
Traditionally used in Chinese medicine to antipyretic/febrifuge/relieve mild fever/reduce body temperature/body cooling
Maintain/support immune system health
Maintain/support healthy immune system function
Decrease/reduce/relieve common cold duration
Helps decrease/reduce/relieve the severity of symptoms of common colds and flu
Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of common colds and flu
 Linked indication - Antipyretic/febrifuge/relieve mild fever/reduce body temperature/body cooling
 Linked indication - Decrease/reduce/relieve cough
Traditionally used in Chinese medicine to decrease/reduce/relieve symptoms of common colds and flu
Decrease/reduce/relieve symptoms of common colds and flu
Traditionally used in Chinese medicine to decrease/reduce/relieve symptoms of common colds and flu
 Linked indication - Decrease/reduce/relieve cough
Decrease/reduce/relieve symptoms of common colds and flu
 Linked indication - Decrease/reduce/relieve cough
Traditionally used in Western herbal medicine to relieve symptoms of mild upper respiratory tract infections
Traditionally used in Chinese medicine to relieve symptoms of mild upper respiratory tract infections
Relieve symptoms of mild upper respiratory tract infections
Relieve symptoms of sore throat/pharyngitis
Traditionally used in Chinese medicine to relieve symptoms of sore throat/pharyngitis
Traditionally used in Western herbal medicine to relieve symptoms of sore throat/pharyngitis

Indication Requirements

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



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

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

Product presentation must not imply or refer to serious immunological diseases.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Andrographis may cause taste disturbance including loss of taste. If you develop any adverse symptoms, stop use and seek medical advice (or words to that effect).

Andrographis may cause allergic reactions in some people. If you have a severe reaction (such as anaphylaxis), stop use and seek immediate medical attention (or words to that effect).

Adults only. OR Not to be used in children under two years of age without medical advice (or words to that effect).

Additional Product information

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Tablet, film coated

Route of Administration Oral

Visual Identification

Active Ingredients

Andrographis paniculata herb Extract dry concentrate standardised	120 mg
Equivalent: Andrographis paniculata (Dry)	6 g
ascorbic acid	250 mg
Echinacea purpurea whole plant Extract dry concentrate	66.7 mg
Equivalent: Echinacea purpurea (Dry)	1 g
Sambucus nigra fruit Juice powder	57.14 mg
Equivalent: Sambucus nigra (Juice fresh)	2 g
zinc amino acid chelate	50 mg
Equivalent: zinc	10 mg

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
colloidal anhydrous silica
croscarmellose sodium
hypromellose
macrogol 400
magnesium stearate
maltodextrin
microcrystalline cellulose
povidone
sodium starch glycollate