



**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

**Public Summary**

<b>Summary for ARTG Entry:</b>	299587	Cold & Flu Strike
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Herbs of Gold Pty Ltd	
<b>Postal Address</b>	PO Box 3143, KIRRAWEE, NSW, 2232 Australia	
<b>ARTG Start Date</b>	13/02/2018	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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	7/07/2021
--------------	-------------------------	----------------	-----------

**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
- 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
- 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 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 relieve symptoms of mild upper respiratory tract infections
- Relieve symptoms of mild upper respiratory tract infections
- Traditionally used in Western herbal medicine to relieve symptoms of mild upper respiratory tract infections
- Traditionally used in Western herbal medicine to relieve symptoms of sore throat/pharyngitis
- Relieve symptoms of sore throat/pharyngitis
- Traditionally used in Chinese medicine to relieve symptoms of sore throat/pharyngitis

**Indication Requirements**

- 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).

Public Summary



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

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 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**

<b>Pack Size</b>	<b>Poison Schedule</b>
------------------	------------------------

**Components**

**1 . Formulation 1**

<b>Dosage Form</b>	Tablet, film coated
<b>Route of Administration</b>	Oral

**Visual Identification**

**Active Ingredients**

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

Public Summary

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.