



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	302367	Nature's Sunshine Andrographis
ARTG entry for	Medicine Listed	
Sponsor	Nature's Sunshine Products of Australia Pty Ltd	
Postal Address	PO Box 6884, BAULKHAM HILLS BUSINESS CENTRE, NSW, 2153 Australia	
ARTG Start Date	27/04/2018	
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.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

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 . Nature's Sunshine Andrographis

Product Type	Single Medicine Product	Effective Date	10/06/2020
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Permitted Indications

- Traditionally used in Ayurvedic medicine to bitter tonic/stimulate gastric secretions
- Maintain/support healthy immune system function
- Decrease/reduce/relieve common cold duration
- Decrease/reduce/relieve mild upper respiratory tract congestion
- Decrease/reduce/relieve the severity of symptoms of mild upper respiratory tract infections
 - Linked indication - Decrease/reduce headache duration
 - Linked indication - Relieve feelings of general malaise/general debility
 - Linked indication - Relieve runny/dripping nose
 - Linked indication - Decrease/reduce/relieve cough
 - Linked indication - Decrease/reduce/relieve mild throat inflammation
 - Linked indication - Unblock/clear nasal passages
 - Linked indication - Decrease/reduce/relieve disturbed/restless sleep
- Decrease/reduce/relieve symptoms of sinusitis
 - Linked indication - Decrease/reduce/relieve sneezing
- Decrease/reduce/relieve the severity of common cold symptoms
- Relieve symptoms of mild upper respiratory tract infections
- Helps reduce occurrence of symptoms of upper respiratory tract infections
- Decrease/reduce/relieve symptoms of common cold
 - Linked indication - Helps decrease/reduce/relieve mild swelling of the glands associated with common cold

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.
- Product presentation must not imply or refer to serious immunological diseases.
- Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.
- Respiratory tract infections must be qualified by 'mild'.

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Product presentation must not imply or refer to mental illnesses, disorders or conditions.

Product presentation must not imply or refer to chronic fatigue syndrome.

Product presentation must only refer to mild gland swelling.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Adults only (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).

If symptoms persist consult your healthcare practitioner (or words to that effect).

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

Andrographis paniculata	100 mg
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Other Ingredients (Excipients)

calcium carbonate

calcium hydrogen phosphate dihydrate

colloidal anhydrous silica

hypromellose

magnesium stearate

purified water

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