



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 333207 Immune +

ARTG entry for Medicine Listed

Sponsor JSHealth Vitamins Pty Ltd

Postal Address 17 Kimberley Street, Vaucluse, NSW, 2030
Australia

ARTG Start Date 2/04/2020

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.

Products

1 . Immune +

| Product Type | Single Medicine Product | Effective Date | 5/01/2023 |
|--------------|-------------------------|----------------|-----------|
|--------------|-------------------------|----------------|-----------|

Permitted Indications

Antioxidant/Reduce free radicals formed in the body

Helps reduce/decrease free radical damage to body cells

Maintain/support immune system health

Maintain/support healthy immune system function

Maintain/support immune system to fight illness

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

- Linked indication - Decrease/reduce/relieve cough
- Linked indication - Decrease/reduce/relieve throat irritation
- Linked indication - Decongestant/relieve nasal congestion
- Linked indication - Decrease/reduce/relieve disturbed/restless sleep
- Linked indication - Decrease/reduce headache duration
- Linked indication - Relieve weariness/tiredness/fatigue/feeling of weakness
- Linked indication - Decrease/reduce ear irritation/inflammation

Maintain/support wound healing

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).

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.

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

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

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings



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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).

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).

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 leaf Extract dry concentrate | 200 mg |
| Equivalent: Andrographis paniculata (Dry) | 4 g |
| ascorbic acid | 250 mg |
| Echinacea purpurea herb Extract dry concentrate | 60 mg |
| Equivalent: Echinacea purpurea (Dry) | 720 mg |
| Olea europaea leaf Extract dry concentrate | 100 mg |
| Equivalent: Olea europaea (Dry) | 1 g |
| Origanum vulgare herb Powder | 50 mg |
| zinc citrate dihydrate | 15.58 mg |
| Equivalent: zinc | 5 mg |
| Zingiber officinale rhizome Extract dry concentrate | 9.09 mg |
| Equivalent: Zingiber officinale (Dry) | 100 mg |

Other Ingredients (Excipients)

Carnauba Wax
colloidal anhydrous silica
croscarmellose sodium
crospovidone
hypromellose
macrogol 400
magnesium stearate
maltodextrin
microcrystalline cellulose
peppermint leaf powder
povidone
pregelatinised rice starch

Public Summary

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