



Australian Government
Department of Health
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.

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 . Immune +

Product Type	Single Medicine Product	Effective Date	2/04/2020
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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 ear irritation/inflammation
Linked indication - Relieve weariness/tiredness/fatigue/feeling of weakness
Linked indication - Decrease/reduce headache duration
Linked indication - Decrease/reduce/relieve throat irritation
Linked indication - Decongestant/relieve nasal congestion
Linked indication - Decrease/reduce/relieve cough
Linked indication - Decrease/reduce/relieve disturbed/restless sleep
Maintain/support wound healing

Indication Requirements

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 immunological diseases.
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 chronic fatigue syndrome.

Standard Indications

No Standard Indications included on Record



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Specific Indications

No Specific Indications included on Record

Warnings

No Warnings included on Record

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

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