



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	376659	Oriental Botanicals Immunity & Stress
ARTG entry for	Medicine Listed	
Sponsor	McPherson's Consumer Products Pty Ltd	
Postal Address	Locked Bag 5018, Kingsgrove, NSW, 2208 Australia	
ARTG Start Date	21/10/2021	
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 . Oriental Botanicals Immunity & Stress

Product Type	Single Medicine Product	Effective Date	21/10/2021
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Permitted Indications

Traditionally used in Ayurvedic medicine to rasayan/rejuvenative tonic
Maintain/support energy production
Maintain/support vitality
Maintain/support immune system health
Traditionally used in Chinese medicine to enhance/improve/promote immune defence/immunity
Traditionally used in Chinese medicine to helps enhance/improve/promote immune system function
Maintain/support healthy immune system function
Traditionally used in Chinese medicine to maintain/support immune system to fight illness
Maintain/support immune system to fight illness
Traditionally used in Chinese medicine to helps stimulate a healthy immune system response
Traditionally used in Western herbal medicine to adaptogen/Help body adapt to stress
Traditionally used in Chinese medicine to adaptogen/Help body adapt to stress
Enhance/promote body adaptation to stress
Traditionally used in Ayurvedic medicine to support healthy stress response in the body
Traditionally used in Ayurvedic medicine to decrease/reduce/relieve symptoms of stress
Decrease/reduce/relieve symptoms of stress
Decrease/reduce/relieve symptoms of mild anxiety
Traditionally used in Chinese medicine to helps reduce occurrence of common colds

Indication Requirements

If Ayurvedic terminology is used on medicine label, label statement: Talk to a Ayurvedic practitioner/health professional if you are unsure if this medicine is right for you.

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

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

Product presentation must only refer to mild anxiety.

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

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



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If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.

Standard Indications

No Standard Indications included on Record

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 Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

ascorbic acid	100 mg
Astragalus membranaceus root Extract dry concentrate	83.33 mg
Equivalent: Astragalus membranaceus (Dry)	1.25 g
colecalfiferol	.0075 mg
Withania somnifera root Extract dry concentrate	300 mg
Equivalent: Withania somnifera (Dry)	3 g
zinc glycinate monohydrate	26.6 mg
Equivalent: zinc	7.5 mg

Other Ingredients (Excipients)

Acacia
colloidal anhydrous silica
disodium edetate
dl-alpha-tocopherol
gellan gum
hypromellose
magnesium stearate
maize starch
medium chain triglycerides
microcrystalline cellulose
potable water
potassium acetate
silicon dioxide
sucrose

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