



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	328695	IMMUNE RX
ARTG entry for	Medicine Listed	
Sponsor	ATP Science Pty Ltd	
Postal Address	5/63-69 Meakin Road, Meadowbrook, QLD, 4131 Australia	
ARTG Start Date	16/01/2020	
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.

The warning statement 'Do not use if pregnant or likely to become pregnant' must be displayed on the medicine label.

Products

1 . IMMUNE RX

Product Type	Single Medicine Product	Effective Date	9/03/2021
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Permitted Indications

Antioxidant/Reduce free radicals formed in the body
Traditionally used in Chinese medicine to maintain/support immune system health
Maintain/support immune system health
Maintain/support healthy immune system function
Traditionally used in Chinese medicine to maintain/support healthy immune system function

Indication Requirements

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

Do not use if pregnant or likely to become pregnant (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

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Visual Identification

Active Ingredients

Artemisia annua leaf Extract dry concentrate	100 mg
Equivalent: Artemisia annua (Fresh)	1 g
Boswellia serrata sap resin Extract dry concentrate	100 mg
Equivalent: Boswellia serrata (Dry)	400 mg
Commiphora myrrha sap resin Extract dry concentrate	75 mg
Equivalent: Commiphora myrrha (Dry)	750 mg
Curcuma longa rhizome Extract dry concentrate	100 mg
Equivalent: Curcuma longa (Dry)	2.5 g
Ganoderma lucidum fruiting body Extract dry concentrate	150 mg
Equivalent: Ganoderma lucidum (Dry)	3 g
Malpighia glabra fruit Extract dry concentrate	138.89 mg
Equivalent: Malpighia glabra (Dry)	3.472 g
Phyllanthus emblica fruit Extract dry concentrate	10 mg
Equivalent: Phyllanthus emblica (Fresh)	100 mg

Other Ingredients (Excipients)

Acacia
colloidal anhydrous silica
hypromellose
magnesium hydroxide
magnesium stearate
maltodextrin
microcrystalline cellulose
purified water

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