Public Summary

Summary for ARTG Entry:	227438 IMMUNE PLEX
ARTG entry for	Medicine Listed
Sponsor	The Pharmaceutical Plant Company Pty Ltd
Postal Address	3 Sigma Drive, Croydon South, VIC, 3136 Australia
ARTG Start Date	1/09/2014
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.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

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 PLEX

Product Type Single Medicine Product **Effective Date** 19/07/2019

Permitted Indications

Traditionally used in Western herbal medicine to enhance/improve/promote immune defence/immunity
Traditionally used in Western herbal medicine to enhance/improve/promote immune defence/immunity in children
Traditionally used in Western herbal medicine to helps enhance/improve/promote immune system function
Traditionally used in Western herbal medicine to helps enhance/improve/promote immune system function in children
Traditionally used in Western herbal medicine to maintain/support healthy immune system function
Traditionally used in Western herbal medicine to maintain/support healthy immune system function in children
Traditionally used in Western herbal medicine to maintain/support immune system to fight illness
Traditionally used in Western herbal medicine to maintain/support immune system to fight illness in children
Traditionally used in Western herbal medicine to adaptogen/Help body adapt to stress
Traditionally used in Western herbal medicine to adaptogen/Help body adapt to stress in children
Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of common colds and flu
Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of common colds and flu in children
Traditionally used in Western herbal medicine to relieve symptoms of mild upper respiratory tract infections
Traditionally used in Western herbal medicine to relieve symptoms of mild upper respiratory tract infections in children

Indication Requirements

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

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

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 forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.

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

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Contains ethanol or contains alcohol.

Not suitable for infants under the age of twelve months (or words to that effect).

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule

Components

1 . Formulation 1

Dosage Form	Oral Liquid
Route of Administration	Oral
Visual Identification	

Active Ingredients

Astragalus membranaceus root Extract liquid	**125 microlitre/mL**
Equivalent: Astragalus membranaceus (Dry)	125 mg/mL
Echinacea purpurea whole plant Extract liquid	**100 microlitre/mL**
Equivalent: Echinacea purpurea (Dry)	100 mg/mL
Ganoderma lucidum whole plant Extract liquid	**200 microlitre/mL**
Equivalent: Ganoderma lucidum (Dry)	200 mg/mL
Olea europaea leaf Extract liquid	**100 microlitre/mL**
Equivalent: Olea europaea (Dry)	100 mg/mL

Other Ingredients (Excipients)

glycerol
Honey
Mentha X piperita
purified water