



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	340387	Berberine ImmunoPlex
ARTG entry for	Medicine Listed	
Sponsor	Herbs of Gold Pty Ltd	
Postal Address	PO Box 3143, KIRRAWEE, NSW, 2232 Australia	
ARTG Start Date	29/07/2020	
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 . Berberine ImmunoPlex

Product Type	Single Medicine Product	Effective Date	12/03/2021
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Permitted Indications

Antioxidant/Reduce free radicals formed in the body
Traditionally used in Chinese medicine to clear/cool/drain/purge/asthenic-heat/deficiency-heat
Traditionally used in Chinese medicine to dispel/expel/disperse/clear fire
Traditionally used in Chinese medicine to remove Heat toxin
Traditionally used in Western herbal medicine to antipyretic/febrifuge/relieve mild fever/reduce body temperature/body cooling
Traditionally used in Western herbal medicine to maintain/support digestive system health
Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of indigestion/dyspepsia
Traditionally used in Western herbal medicine to maintain/support liver health
Maintain/support immune system health
Traditionally used in Western herbal medicine to maintain/support immune system health
Maintain/support healthy immune system function
Traditionally used in Western herbal medicine to maintain/support healthy immune system function
Traditionally used in Western herbal medicine to decrease/reduce/relieve bronchial mucous congestion
Traditionally used in Western herbal medicine to decrease/reduce excess mucous
Traditionally used in Western herbal medicine to expectorant/clear respiratory tract mucous
Traditionally used in Western herbal medicine to decrease/reduce/relieve cough
Traditionally used in Western herbal medicine to relieve symptoms of sore throat/pharyngitis

Indication Requirements

Label statement: Not to be used in children under 5 years.

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.

Product presentation must not imply or refer to gastro oesophageal reflux disease.

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

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

Label statement: Adults only, OR Not to be used in children under 2 years of age without medical advice (or words to that effect).



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Product presentation must only refer to detoxification in relation to natural body processes.

Product presentation must not imply or refer to disease in any body organ, in particular the kidney or liver.

Product presentation must not imply or refer to drugs/alcohol.

Product presentation must not imply or refer to liver disease, such as cirrhosis, hepatitis.

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 Tablet, film coated

Route of Administration Oral

Visual Identification

Active Ingredients

Berberis vulgaris stem bark Extract dry concentrate	75 mg
Equivalent: Berberis vulgaris (Dry)	750 mg
Handroanthus impetiginosus stem bark inner Extract dry concentrate	75 mg
Equivalent: Handroanthus impetiginosus (Dry)	750 mg
Phellodendron amurense stem bark Extract dry concentrate	424 mg
Equivalent: Phellodendron amurense (Dry)	4.24 g
Thymus vulgaris leaf Extract dry concentrate	125 mg
Equivalent: Thymus vulgaris (Dry)	500 mg
Uncaria tomentosa stem bark Extract dry concentrate	375 mg
Equivalent: Uncaria tomentosa (Dry)	1.5 g

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
Carnauba Wax
colloidal anhydrous silica
croscarmellose sodium
crospovidone
hypromellose
macrogol 400
magnesium stearate
microcrystalline cellulose
povidone

Public Summary

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