



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	357411	Alpha GanoPoly B+
ARTG entry for	Medicine Listed	
Sponsor	Alpha Bio-Tech Aust Pty Ltd	
Postal Address	Suite 39 / 650 George Street, World Square, Sydney, NSW, 2000 Australia	
ARTG Start Date	23/03/2021	
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 . Alpha GanoPoly B+

Product Type	Single Medicine Product	Effective Date	1/06/2022
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Permitted Indications

- Traditionally used in Chinese medicine to maintain/support general health and wellbeing
- Traditionally used in Chinese medicine to maintain/support general health and wellbeing
- Traditionally used in Chinese medicine to maintain/support cardiovascular system health
- Traditionally used in Chinese medicine to enhance/improve/promote immune defence/immunity
- Traditionally used in Chinese medicine to decrease/reduce/relieve cough

Indication Requirements

Product presentation must not imply or refer to serious cardiovascular 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

No Warnings included on Record

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form Capsule, hard

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Route of Administration Oral

Visual Identification

Active Ingredients

Alisma orientale tuber Extract dry concentrate	50 mg
Equivalent: Alisma orientale (Fresh)	1 g
Astragalus membranaceus root Extract dry concentrate	100 mg
Equivalent: Astragalus membranaceus (Fresh)	2 g
Ganoderma lucidum fruiting body Extract dry concentrate	150 mg
Equivalent: Ganoderma lucidum (Fresh)	3 g
Ginkgo biloba seed Extract dry concentrate	75 mg
Equivalent: Ginkgo biloba (Fresh)	1.5 g
Pueraria lobata root Extract dry concentrate	75 mg
Equivalent: Pueraria lobata (Fresh)	1.5 g
Salvia miltiorrhiza root and rhizome Extract dry concentrate	50 mg
Equivalent: Salvia miltiorrhiza (Fresh)	1 g

Other Ingredients (Excipients)

brilliant blue FCF
erythrosine
Gelatin
purified water
sodium lauryl sulfate
sunset yellow FCF
titanium dioxide

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