



ARTG Certificate

Issued to
Sumabe Pty Ltd
 for approval to supply
Allselve Coffee

ARTG Identifier **AUST L 162010**
 ARTG Start date **26/05/2009**
 Product type: **Listed Medicine**
 Export Names Allselve Coffee Lite
 Detox Green Coffee
 Green Coffee for Slimers

Manufacturer(s) Details	Address	Manufacturing steps
DFC-Pharmamed Pty Ltd	23-25 Sefton Road THORNLEIGH, NSW, 2120 Australia	Manufacture of dosage form Packaging and labelling Release for supply Secondary packaging
EML Consulting Services Pty Ltd	Unit 2 9-11 South Street RYDALMERE, NSW, 2116 Australia	Testing microbial
Labmark Pty Ltd	Units 1 & 16 & 17 / 8 Leighton Place ASQUITH, NSW, 2077 Australia	Testing chemical and physical

ARTG Standard Conditions

The above Medicine Listed has been entered on the Register subject to the following conditions:

- Colouring agents used in listed medicine for ingestion, other than those listed for export only under section 25 of the Therapeutic Goods Act 1989, shall be only those included in the list of 'Colourings permitted in medicines for oral use' available at <<http://www.tga.gov.au/meds/colourings.htm>>, as amended from time to time.
- 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 Head, Office of Complementary Medicines, Therapeutic Goods Administration, upon the head's 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 Director, Adverse Drug Reactions Unit, 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 Medicines Safety Monitoring 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 Head, Office of Complementary Medicines, Therapeutic Goods Administration, immediately the action or information is known to the sponsor.

Products covered by this Entry

1. Allselve Coffee

Product Specific Conditions

No specific conditions have been recorded against this entry.

Product Standard Indications

- May assist blood circulation.
- Liver tonic.
- Formula to support the liver.

Product Specific Indications

- May help maintain healthy (and or normal) cholesterol levels.
 May help to maintain cholesterol levels within the normal (and or healthy) range and improve HDL:LDL ratio.
 Supports/helps maintain healthy immune function.
 Provides support to the immune system.
 Supports healthy immune mechanisms.
 Contains ganoderma lucidium, which has antioxidant activity and may therefore assist in protecting the body from potential free radical damage.
 Antioxidant/free radical scavenger.
 Has antioxidant activity and therefore assists in protecting against oxidative/free radical damage.
 Supports healthy liver detoxification processes.
 Supports/maintains healthy liver function.
 Ganoderma lucidium has a long history of use in Traditional Chinese Medicine to reduce mucous congestion, relieve cough and reduce wheezing.
 Ganoderma lucidium has traditionally been used to reduce cough due to cold and coughs with excess phlegm.
 In Traditional Chinese Medicine Ganoderma lucidium is used to strengthen the body and tonify qi and blood.
 Ganoderma lucidium has traditionally been used in the Chinese Medicine system to reduce fatigue and listlessness.
 In Traditional Chinese Medicine, Ganoderma lucidium is used to strengthen poor digestion and improve the appetite.
 May be used in conjunction with a healthy diet and exercise programme to support weight loss.

May assist in decreasing body fat when combines with exercise and a health diet.
Supports a healthy body composition.
May help to reduce fatigue.
Helps to improve alertness and energy levels.

Warnings

- Use in children under 12 years is not recommended. (CHILD3)
- Adults only. OR Not to be used in children under two years of age without medical advice (or words to that effect). (COLD)
- Adults only. OR Not to be used in children under two years of age without medical advice (or words to that effect). (COU1)
- Prolonged use may cause serious bowel problems. (LAX2)
- Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product (or words to that effect). (LAX3)
- If symptoms persist consult your healthcare practitioner (or words to that effect). (S)

Dosage Form

Powder, oral

Route of Administration

Oral

Visual Identification

Not recorded

Product Formulation(s)

Active Ingredients

	Quantity	Units
Glycine max	50	mg/g
Cassia tora	50	mg/g
Rosa canina	100	mg/g
Coffea arabica	650	mg/g
Ganoderma lucidum	150	mg/g

END OF CERTIFICATE

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