



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	282724	AMA Care - Liver Detox Formula
ARTG entry for	Medicine Listed	
Sponsor	Cheella Healthcare Pty Ltd	
Postal Address	193 Botanica Springs Boulevard, Brookfield, VIC, 3338 Australia	
ARTG Start Date	21/11/2016	
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 . AMA Care - Liver Detox Formula

Product Type	Single Medicine Product	Effective Date	6/11/2021
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Permitted Indications

Traditionally used in Ayurvedic medicine to aids/assists natural cleansing/detoxification processes of the gastrointestinal system/gut

Traditionally used in Ayurvedic medicine to maintain/support natural liver cleansing/detoxification processes

Traditionally used in Ayurvedic medicine to vipachini/aids digestion

Traditionally used in Ayurvedic medicine to twak roga hara/supports skin health

Maintain/support general health and wellbeing

Traditionally used in Ayurvedic medicine to decrease/reduce/relieve constipation

Traditionally used in Ayurvedic medicine to decrease/reduce/relieve excess intestinal gas

Traditionally used in Ayurvedic medicine to decrease/reduce/relieve abdominal bloating/distention

Traditionally used in Ayurvedic medicine to digestive tonic/Improve digestive weakness

Traditionally used in Ayurvedic medicine to maintain/support immune system health

Traditionally used in Ayurvedic medicine to enhance/improve/promote immune defence/immunity

Traditionally used in Ayurvedic medicine to helps enhance/improve/promote immune system function

Traditionally used in Ayurvedic medicine to maintain/support healthy immune system function

Aid/assist/helps glucose/sugar/carbohydrate metabolism

Traditionally used in Ayurvedic medicine to relieve symptoms of acne

Traditionally used in Ayurvedic medicine to decrease/reduce/relieve symptoms of mild eczema/dermatitis

Traditionally used in Ayurvedic medicine to decrease/reduce/relieve symptoms of mild psoriasis

Indication Requirements

Product presentation must not refer to or imply weight loss.

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

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

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

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

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

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

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Label statement for stimulant laxatives: Prolonged use may cause serious bowel problems.

Label statement: Do not use when abdominal pain, nausea or vomiting are present or if you develop diarrhoea. If you are pregnant or breastfeeding - seek the advice of a healthcare professional before taking this product (or words to that effect).

Product presentation must not imply or refer to lowering or raising blood sugar/glucose levels from outside of the normal healthy range.

Product presentation must only refer to mild eczema.

Product presentation must only refer to mild psoriasis

Label statement: Drink plenty of water (or words to that effect).

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

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Not recommended for use by pregnant and lactating women (or words to that effect).

Andrographis may cause allergic reactions in some people. If you have a severe reaction (such as anaphylaxis), stop use and seek immediate medical attention (or words to that effect).

If symptoms persist consult your healthcare practitioner (or words to that effect).

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).

Prolonged use may cause serious bowel problems.

Drink plenty of water (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

Visual Identification

Active Ingredients

Andrographis paniculata herb Extract dry concentrate	100 mg
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Equivalent: Andrographis paniculata (Dry)	700 mg
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Cedrus deodara rhizome heartwood Extract dry concentrate	50 mg
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Equivalent: Cedrus deodara (Dry)	500 mg
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Phyllanthus amarus herb Extract dry concentrate	200 mg
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Equivalent: Phyllanthus amarus (Dry)	1.8 g
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Phyllanthus emblica fruit Extract dry concentrate	100 mg
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Equivalent: Phyllanthus emblica (Dry)	300 mg
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Other Ingredients (Excipients)

colloidal anhydrous silica

croscarmellose sodium

hypromellose

magnesium stearate

microcrystalline cellulose

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