



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	377831	Aden Complex
ARTG entry for	Medicine Listed	
Sponsor	Interclinical Laboratories Pty Ltd	
Postal Address	PO Box 6474, ALEXANDRIA, NSW, 2015 Australia	
ARTG Start Date	12/11/2021	
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 . Aden Complex

Product Type	Single Medicine Product	Effective Date	7/12/2021
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Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Maintain/support collagen formation
- Traditionally used in Ayurvedic medicine to medhya/brain tonic/improve memory and cognition
- Traditionally used in Ayurvedic medicine to kasa hara/relieve cough
- Traditionally used in Ayurvedic medicine to balya/improve body strength
- Traditionally used in Ayurvedic medicine to vrishya/aphrodisiac/Increase in virility
- Traditionally used in Ayurvedic medicine to rasayan/rejuvenative tonic
- Traditionally used in Chinese medicine to remove Heat toxin
- Traditionally used in Chinese medicine to tonify/nourish/strengthen/replenish Qi
- Traditionally used in Chinese medicine to tonify/nourish/strengthen/replenish spleen-qi
- Maintain/support energy levels
- Maintain/support energy production
- Maintain/support physical endurance/capacity/stamina
- Traditionally used in Chinese medicine to relieve weariness/tiredness/fatigue/feeling of weakness
- Maintain/support healthy eye function
- Traditionally used in Ayurvedic medicine to maintain/support eye health
- Maintain/support eye health
- Helps maintain/support eye macula health
- Helps maintain/support eye retina health
- Maintain/support healthy eyesight/vision
- Traditionally used in Chinese medicine to body tonic
- Traditionally used in Chinese medicine to maintain/support general health and wellbeing
- Traditionally used in Western herbal medicine to maintain/support general health and wellbeing
- Traditionally used in Ayurvedic medicine to maintain/support general health and wellbeing
- Maintain/support general health and wellbeing
- Maintain/support hair health
- Maintain/support healthy teeth

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Maintain/support nail health/strength/thickness
Traditionally used in Ayurvedic medicine to antipyretic/febrifuge/relieve mild fever/reduce body temperature/body cooling

Maintain/support connective tissue health
Aid/assist/helps connective tissue production/formation
Traditionally used in Western herbal medicine to demulcent/soothe irritated tissues

Maintain/support bone health
Aid/assist healthy red blood cell production
Helps maintain/support haemoglobin formation/synthesis

Maintain/support cardiovascular system health
Maintain/support healthy cardiovascular system function

Maintain/support heart health
Maintain/support blood capillary health
Maintain/support blood vessel health
Traditionally used in Western herbal medicine to maintain/support adrenal gland health
Traditionally used in Western herbal medicine to maintain/support healthy adrenal gland function
Traditionally used in Chinese medicine to decrease/reduce/relieve loss of appetite
Traditionally used in Ayurvedic medicine to decrease/reduce/relieve diarrhoea
Traditionally used in Ayurvedic medicine to decrease/reduce/relieve colic (wind/gas pain)
Traditionally used in Western herbal medicine to sialagogue/promote saliva production
Traditionally used in Chinese medicine to decrease/reduce/relieve abdominal spasm

Maintain/support immune system health
Maintain/support healthy immune system function

Maintain/support muscle function
Aid/assist/helps protein synthesis in the body
Maintain/support absorption of dietary (state vitamin/mineral/nutrient)
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)
Aids/assists the body to cope with environmental stress
Support healthy stress response in the body

Maintain/support mental concentration/focus/clarity
Maintain/support cognitive function/mental function
Maintain/support nerve conduction
Aid/assist/helps synthesis of neurotransmitters
Maintain/support nervous system health
Traditionally used in Ayurvedic medicine to nervine/support nervous system

Maintain/support nervous system function
Traditionally used in Ayurvedic medicine to maintain/support female reproductive system health

Maintain/support female reproductive system health
Maintain/support preconception health in healthy males
Maintain/support preconception health in healthy females
Maintain/support reproductive system health in males
Traditionally used in Ayurvedic medicine to maintain/support reproductive system health

Maintain/support healthy reproductive hormones
Traditionally used in Ayurvedic medicine to aphrodisiac/Enhance/improve/promote healthy libido

Maintain/support sperm health in healthy males
Maintain/support sperm production in healthy males
Maintain/support testosterone level
Traditionally used in Western herbal medicine to decrease/reduce/relieve bronchial mucous congestion
Traditionally used in Chinese medicine to expectorant/clear respiratory tract mucous
Traditionally used in Western herbal medicine to expectorant/clear respiratory tract mucous
Traditionally used in Chinese medicine to decrease/reduce/relieve cough
Traditionally used in Western herbal medicine to decrease/reduce/relieve cough
Traditionally used in Ayurvedic medicine to relieve hoarseness of voice

Maintain/support skin health
Maintain/support skin integrity/structure

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Maintain/support skin regeneration
 Maintain/support wound healing

Indication Requirements

Label statement: Adults only, OR Not to be used in children under 2 years of age without medical advice (or words to that effect).
 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.
 Product presentation must not imply or refer to vision correction, faults or serious eye disease e.g. macular degeneration.

Label statement: Not to be used in children under 5 years.
 Product presentation must not imply or refer to serious cardiovascular conditions.
 Product presentation must not imply or refer to mental illnesses, disorders or conditions.
 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 eating disorders.
 Product presentation must not imply or refer to serious immunological diseases.

Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
 Product presentation must not imply or refer to hormone imbalances.

Label statement: If symptoms persist, talk to your health professional.
 Product presentation must not imply or refer to infertility.

If directed to women, Label statement: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester.
 If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.

Label statement: Seek medical advice if diarrhoea persists for more than: 6 hours in infants under 6 months, 12 hours in children under 3 years, 24 hours in children aged 3 to 6 years or 48 hours in adults and children over 6 years (or words to that effect).
 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 chronic fatigue syndrome.
 Product presentation must not imply or refer to any adrenal related diseases.
 Product presentation must not imply or refer to drugs/alcohol.
 Product presentation must not imply or refer to circulatory disorders/diseases/conditions e.g. thrombosis.
 Product presentation must not imply or refer to disease in any body organ.
 Product presentation must not imply or refer to gastro oesophageal reflux disease.
 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 bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.
 Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.
 Product presentation must only refer to detoxification in relation to natural body processes.

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	Tablet, film coated
Route of Administration	Oral

Visual Identification

Active Ingredients

ascorbic acid	60 mg
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Asparagus racemosus root Extract dry concentrate	300 mg
Equivalent: Asparagus racemosus (Dry)	5.1 g
calcium pantothenate	10.87 mg
Equivalent: pantothenic acid	10 mg
dibasic sodium phosphate	100 mg
Equivalent: sodium	32.39 mg
Glycyrrhiza glabra root Extract dry concentrate standardised	36.36 mg
Equivalent: Glycyrrhiza glabra (Dry)	999.9 mg
lutein	1.5 mg
monobasic potassium phosphate	139.23 mg
Equivalent: potassium	40 mg
Panax ginseng root Extract dry concentrate standardised	15 mg
Equivalent: Panax ginseng (Dry)	150 mg
pyridoxine hydrochloride	1.25 mg
Equivalent: pyridoxine	1.03 mg
thiamine nitrate	1.23 mg
Equivalent: thiamine	1 mg
zinc glycinate	10.64 mg
Equivalent: zinc	3 mg
Zingiber officinale rhizome Extract dry concentrate	20 mg
Equivalent: Zingiber officinale (Dry)	100 mg
Other Ingredients (Excipients)	
ascorbyl palmitate	
calcium phosphate	
citric acid	
colloidal anhydrous silica	
croscarmellose sodium	
hypromellose	
hypromellose	
magnesium stearate	
maltodextrin	
microcrystalline cellulose	
zeaxanthin	

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