



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	377831	Aden Complex
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Interclinical Laboratories Pty Ltd	
<b>Postal Address</b>	PO Box 6474, ALEXANDRIA, NSW, 2015 Australia	
<b>ARTG Start Date</b>	12/11/2021	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	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

Public Summary



**Australian Government**  
**Department of Health**  
**Therapeutic Goods Administration**

**Public Summary**

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 females  
Maintain/support preconception health in healthy males  
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



**Australian Government**  
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Maintain/support skin regeneration  
Maintain/support wound healing

#### Indication Requirements

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).

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 hormone imbalances.

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).

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).

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 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
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Route of Administration	Oral
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#### Visual Identification

#### Active Ingredients

ascorbic acid	60 mg
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**Department of Health**  
Therapeutic Goods Administration

<b>Asparagus racemosus root Extract dry concentrate</b>	<b>300 mg</b>
Equivalent: Asparagus racemosus (Dry)	5.1 g
<b>calcium pantothenate</b>	<b>10.87 mg</b>
Equivalent: pantothenic acid	10 mg
<b>dibasic sodium phosphate</b>	<b>100 mg</b>
Equivalent: sodium	32.39 mg
<b>Glycyrrhiza glabra root Extract dry concentrate standardised</b>	<b>36.36 mg</b>
Equivalent: Glycyrrhiza glabra (Dry)	999.9 mg
<b>lutein</b>	<b>1.5 mg</b>
<b>monobasic potassium phosphate</b>	<b>139.23 mg</b>
Equivalent: potassium	40 mg
<b>Panax ginseng root Extract dry concentrate standardised</b>	<b>15 mg</b>
Equivalent: Panax ginseng (Dry)	150 mg
<b>pyridoxine hydrochloride</b>	<b>1.25 mg</b>
Equivalent: pyridoxine	1.03 mg
<b>thiamine nitrate</b>	<b>1.23 mg</b>
Equivalent: thiamine	1 mg
<b>zinc glycinate</b>	<b>10.64 mg</b>
Equivalent: zinc	3 mg
<b>Zingiber officinale rhizome Extract dry concentrate</b>	<b>20 mg</b>
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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Public Summary