



Australian Government

Department of Health, Disability and Ageing  
Therapeutic Goods Administration

Public Summary

<b>Summary for ARTG Entry:</b>	407505	Healthy Skin Support
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Whole Health Studio	
<b>Postal Address</b>	4 Glenelg Avenue, Mermaid Beach, QLD, 4218 Australia	
<b>ARTG Start Date</b>	11/04/2023	
<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 . Healthy Skin Support**

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	4/05/2023
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**Permitted Indications**

- Antioxidant/Reduce free radicals formed in the body when dietary intake is inadequate
- Antioxidant/Reduce free radicals formed in the body
- Maintain/support collagen formation when dietary intake is inadequate
- Traditionally used in Western herbal medicine to alterative/blood cleanser/depurative/purifier
- Traditionally used in Western herbal medicine to aids/assists natural body cleansing/detoxification processes
- Traditionally used in Western herbal medicine to aids/assists excretion of metabolic waste products
- Maintain/support healthy eye function
- Maintain/support eye health
- Maintain/support healthy eyesight/vision
- Traditionally used in Western herbal medicine to sudorific/diaphoretic/enhance/promote sweating/perspiration
- Traditionally used in Western herbal medicine to body tonic
- Traditionally used in Western herbal medicine to restorative tonic
- Maintain/support general health and wellbeing when dietary intake is inadequate
- Traditionally used in Western herbal medicine to maintain/support general health and wellbeing
- Maintain/support general health and wellbeing
- Maintain/support hair growth
- Maintain/support hair health
- Maintain/support hair strength/thickness
- Maintain/support healthy teeth when dietary intake is inadequate
- Maintain/support nail health/strength/thickness
- Traditionally used in Western herbal medicine to antipyretic/febrifuge/relieve mild fever/reduce body temperature/body cooling
- Maintain/support connective tissue health when dietary intake is inadequate
- Aid/assist/helps connective tissue production/formation when dietary intake is inadequate
- Maintain/support blood capillary health when dietary intake is inadequate
- Maintain/support blood vessel health when dietary intake is inadequate
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of mild varicose veins
- Traditionally used in Western herbal medicine to decrease/reduce/relieve loss of appetite

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Traditionally used in Western herbal medicine to aperient/laxative  
Traditionally used in Western herbal medicine to decrease/reduce/relieve colic (wind/gas pain)  
Traditionally used in Western herbal medicine to decrease/reduce/relieve flatulence/carminative  
Traditionally used in Western herbal medicine to decrease/reduce/relieve abdominal spasm  
Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of indigestion/dyspepsia  
Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of indigestion/dyspepsia  
Traditionally used in Western herbal medicine to relieve digestive discomfort  
Traditionally used in Western herbal medicine to digestive tonic/Improve digestive weakness  
Traditionally used in Western herbal medicine to maintain/support gallbladder function  
Traditionally used in Western herbal medicine to hepatoprotectant/protect the liver  
Traditionally used in Western herbal medicine to maintain/support healthy liver function  
Maintain/support immune system health  
Maintain/support immune system health when dietary intake is inadequate  
Maintain/support healthy immune system function  
Maintain/support healthy immune system function when dietary intake is inadequate  
Aid/assist/helps protein synthesis in the body  
Maintain/support absorption of dietary (state vitamin/mineral/nutrient) when dietary intake is inadequate  
Maintain/support (state vitamin/mineral/nutrient) levels in the body when dietary intake is inadequate  
Maintain/support (state vitamin/mineral/nutrient) levels in the body  
Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)  
Maintain/support (state vitamin/mineral) within normal range when dietary intake is inadequate  
Maintain/support (state vitamin/mineral) within normal range  
Maintain/support nerve conduction  
Aid/assist/helps synthesis of neurotransmitters when dietary intake is inadequate  
Maintain/support nervous system health when dietary intake is inadequate  
Maintain/support nervous system function  
Maintain/support nervous system function when dietary intake is inadequate  
Maintain/support female reproductive system health  
Maintain/support/regulate healthy menstrual cycle  
Maintain/support reproductive system health in males  
Maintain/support healthy reproductive hormones  
Maintain/support testosterone level  
Traditionally used in Western herbal medicine to relieve symptoms of acne  
Traditionally used in Western herbal medicine to relieve minor skin eruptions  
Traditionally used in Western herbal medicine to decrease/reduce/relieve pimples  
Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of mild psoriasis  
Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of boils  
Maintain/support skin health  
Maintain/support skin health when dietary intake is inadequate  
Maintain/support skin integrity/structure  
Maintain/support skin regeneration  
Maintain/support wound healing  
Maintain/support wound healing when dietary intake is inadequate  
Traditionally used in Western herbal medicine to aid/assist flushing of the urinary tract  
Traditionally used in Western herbal medicine to enhance/promote/increase urine output

**Indication Requirements**

Product presentation must only refer to mild psoriasis  
Label statement: If symptoms persist, talk to your health professional.  
Product presentation must only refer to detoxification in relation to natural body processes.  
Product presentation must not imply or refer to drugs/alcohol.  
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 eating disorders.  
If product is indicated for supplementation, 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).



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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 mental illnesses, disorders or conditions.

Product presentation must not imply or refer to hormone imbalances.

Product presentation must not imply or refer to vision correction, faults or serious eye disease e.g. macular degeneration.

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

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

Product presentation must only refer to mild varicose veins.

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 refer to or imply weight loss.

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

Product presentation must not encourage excessive or harmful consumption of alcohol or other toxic substances.

Product presentation must not imply or refer to liver disease, such as cirrhosis, hepatitis.

Label statement: Not to be used in children under 5 years.

Product presentation must not imply or refer to kidney disease.

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

Product presentation must not imply or refer to infertility.

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.

**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

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

<b>Arctium lappa root Extract dry concentrate</b>	<b>100 mg</b>
Equivalent: Arctium lappa (Dry)	1 g
<b>ascorbic acid</b>	<b>30 mg</b>
<b>Calendula officinalis flower Extract dry concentrate</b>	<b>50 mg</b>
Equivalent: Calendula officinalis (Dry)	500 mg
<b>Echinacea angustifolia root Extract dry concentrate</b>	<b>75 mg</b>
Equivalent: Echinacea angustifolia (Dry)	750 mg
<b>Echinacea purpurea root Extract dry concentrate</b>	<b>150 mg</b>
Equivalent: Echinacea purpurea (Dry)	1.5 g
<b>Glycyrrhiza glabra root Extract dry concentrate</b>	<b>19.23 mg</b>
Equivalent: Glycyrrhiza glabra (Dry)	250 mg
<b>Silybum marianum fruit Extract dry concentrate</b>	<b>156.25 mg</b>
Equivalent: Silybum marianum (Dry)	10.94 g
<b>zinc citrate dihydrate</b>	<b>22.37 mg</b>
Equivalent: zinc	

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<b>Zingiber officinale rhizome Extract dry concentrate</b>	7 mg
Equivalent: Zingiber officinale (Dry)	<b>30 mg</b>
	330 mg

**Other Ingredients (Excipients)**

colloidal anhydrous silica

hypromellose

maltodextrin

purified water

silicon dioxide

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