



**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

**Public Summary**

<b>Summary for ARTG Entry:</b>	312837	Skin + Digestion
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	JSHealth Vitamins Pty Ltd	
<b>Postal Address</b>	17 Kimberley Street, Vaucluse, NSW, 2030 Australia	
<b>ARTG Start Date</b>	28/12/2018	
<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.

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 Head, Office of Product Review, 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 Product Review 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 National Manager Therapeutic Goods Administration, immediately the action or information is known to the sponsor.

**Products**

**1 . Skin + Digestion**

Product Type	Single Medicine Product	Effective Date	28/12/2018
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**Permitted Indications**

- Antioxidant/Reduce free radicals formed in the body
- Helps reduce/decrease free radical damage to body cells
- Maintain/support collagen formation
- Traditionally used in Western herbal medicine to alterative/blood cleanser/depurative/purifier
- Helps convert (state food) into energy
- Helps maintain/support healthy acid/alkali balance in the body
- Maintain/support body mucous membrane health
- Maintain/support general health and wellbeing
- Maintain/support connective tissue health
- Aid/assist/helps connective tissue production/formation
- Maintain/support healthy body tissues
- Maintain/support bone health
- Helps maintain/supports healthy joint cartilage growth/development/production
- Maintain/support blood capillary health
- Maintain/support gastrointestinal system health
- Traditionally used in Western herbal medicine to relieve digestive discomfort
- Traditionally used in Western herbal medicine to helps enhance/improve/promote/increase bile secretion/flow
- Traditionally used in Western herbal medicine to promote bile flow from liver/chloretic
- Maintain/support immune system health

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Maintain/support healthy immune system function  
 Aid/assist/helps protein synthesis in the body  
 Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)  
 Aid/assist/helps synthesis of neurotransmitters  
 Relieve symptoms of acne  
 Traditionally used in Western herbal medicine to relieve minor skin eruptions  
 Relieve minor skin eruptions  
 Decrease/reduce/relieve pimples  
 Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of mild eczema/dermatitis  
 Maintain/support skin health  
 Maintain/support wound healing

**Indication Requirements**

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

Product presentation must only refer to mild eczema.

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

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 not imply or refer to drugs/alcohol.

Label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.

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, in particular the kidney or liver.

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

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

**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

No Specific Indications included on Record

**Warnings**

WARNING: May be dangerous if taken in large amounts or for a long period. OR WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).

**Additional Product information**

**Pack Size/Poison information**

**Pack Size** **Poison Schedule**

**Components**

**1 . Formulation 1**

**Dosage Form** Tablet, film coated

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

<b>Aloe vera leaf Extract dry concentrate</b>	<b>2 mg</b>
Equivalent: Aloe vera (Dry)	400 mg
<b>Arctium lappa root Extract dry concentrate</b>	<b>50 mg</b>
Equivalent: Arctium lappa (Dry)	1 g
<b>ascorbic acid</b>	<b>50 mg</b>
<b>calcium pantothenate</b>	<b>21.84 mg</b>
Equivalent: pantothenic acid	20 mg
<b>Calendula officinalis flower Extract dry concentrate</b>	<b>40 mg</b>
Equivalent: Calendula officinalis (Dry)	400 mg



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<b>colloidal anhydrous silica</b>	<b>215 mg</b>
Equivalent: silicon	100 mg
<b>Curcuma longa rhizome Extract dry concentrate</b>	<b>75 mg</b>
Equivalent: Curcuma longa (Dry)	750 mg
<b>d-alpha-tocopheryl acetate</b>	<b>36.77 mg</b>
Equivalent: d-alpha-tocopheryl acetate	25 IU
<b>Gentiana lutea root Extract dry concentrate</b>	<b>7.5 mg</b>
Equivalent: Gentiana lutea (Dry)	75 mg
<b>glutamine</b>	<b>250 mg</b>
<b>lysine hydrochloride</b>	<b>187.5 mg</b>
Equivalent: lysine	150 mg
<b>pectin</b>	<b>50 mg</b>
<b>pyridoxine hydrochloride</b>	<b>12.16 mg</b>
Equivalent: pyridoxine	10 mg
<b>quercetin dihydrate</b>	<b>56 mg</b>
Equivalent: quercetin	50 mg
<b>riboflavin sodium phosphate</b>	<b>26.67 mg</b>
Equivalent: riboflavin	20 mg
<b>zinc citrate dihydrate</b>	<b>46.74 mg</b>
Equivalent: zinc	15 mg
<b>Zingiber officinale root Extract dry concentrate</b>	<b>20 mg</b>
Equivalent: Zingiber officinale (Dry)	200 mg

**Other Ingredients (Excipients)**

calcium hydrogen phosphate dihydrate  
Carnauba Wax  
chlorophyllin-copper complex  
colloidal anhydrous silica  
croscarmellose sodium  
crospovidone  
hypromellose  
macrogol 400  
macrogol 8000  
magnesium stearate  
microcrystalline cellulose  
povidone  
pregelatinised maize starch

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