



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

**Public Summary**

<b>Summary for ARTG Entry:</b>	375784	Collagen Hair Health
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Gelpro Australia Pty Ltd	
<b>Postal Address</b>	90 Darcy Road, Wentworthville, NSW, 2145 Australia	
<b>ARTG Start Date</b>	5/10/2021	
<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 . Collagen Hair Health**

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	23/12/2021
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**Permitted Indications**

- Antioxidant/Reduce free radicals formed in the body
- Maintain/support collagen formation
- Maintain/support energy levels
- Helps convert (state food) into energy
- Maintain/support energy production
- Maintain/support body mucous membrane health
- Maintain/support general health and wellbeing
- Maintain/support hair health
- Maintain/support nail health/strength/thickness
- Maintain/support connective tissue health
- Aid/assist/helps connective tissue production/formation
- Maintain/support healthy thyroid gland function
- Maintain/support healthy thyroid hormones
- Maintain/support thyroid gland health
- Aid/assist thyroid hormone production
- Maintain/support immune system health
- Maintain/support healthy immune system 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)
- Maintain/support skin health
- Maintain/support skin integrity/structure
- Maintain/support skin regeneration
- Maintain/support wound healing

**Indication Requirements**



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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).

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).

Product presentation must not imply or refer to any thyroid related diseases.

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

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: If symptoms persist, talk to your health professional.

Product presentation must not imply or refer to chronic fatigue syndrome.

**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

No Specific Indications included on Record

**Warnings**

This medicine contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.

**Additional Product information**

**Pack Size/Poison information**

<b>Pack Size</b>	<b>Poison Schedule</b>
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**Components**

**1 . Formulation 1**

<b>Dosage Form</b>	Tablet, film coated
<b>Route of Administration</b>	Oral

**Visual Identification**

**Active Ingredients**

<b>ascorbic acid</b>	<b>100 mg</b>
<b>Bambusa breviflora leaf Extract dry concentrate</b>	<b>71.43 mg</b>
Equivalent: Bambusa breviflora (Dry)	2.1429 g
<b>Biotin</b>	<b>1 mg</b>
<b>cyanocobalamin</b>	<b>.01 mg</b>
<b>hydrolysed collagen</b>	<b>50 mg</b>
<b>potassium iodide</b>	<b>.1635 mg</b>
Equivalent: iodine	.125 mg
<b>pyridoxine hydrochloride</b>	<b>6.08 mg</b>
Equivalent: pyridoxine	5 mg
<b>selenomethionine</b>	<b>.1242 mg</b>
Equivalent: selenium	.05 mg
<b>Undaria pinnatifida leaf Powder</b>	<b>250 mg</b>
Equivalent: Undaria pinnatifida (Dry)	250 mg
<b>zinc citrate dihydrate</b>	<b>31.15 mg</b>
Equivalent: zinc	10 mg

**Other Ingredients (Excipients)**

**Carnauba Wax**  
**colloidal anhydrous silica**  
**croscarmellose sodium**  
**crospovidone**  
**hypromellose**  
**macrogol 400**

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magnesium stearate  
microcrystalline cellulose  
povidone  
pregelatinised rice starch

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