



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

## Public Summary

<b>Summary for ARTG Entry:</b>	377114	Pure Collagen Peptides + C
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Thera Health Pty Ltd	
<b>Postal Address</b>	18/93 Rivergate Place, Murarrie, QLD, 4172 Australia	
<b>ARTG Start Date</b>	29/10/2021	
<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 . Pure Collagen Peptides + C

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	29/10/2021
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### Permitted Indications

Antioxidant/Reduce free radicals formed in the body  
Maintain/support collagen formation  
Maintain/support general health and wellbeing  
Aid/assist/helps connective tissue production/formation  
Maintain/support bone health  
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency  
Maintain/support skin health  
Maintain/support skin hydration  
Maintain/support skin elasticity  
Maintain/support skin integrity/structure  
Maintain/support skin repair/healing/regeneration

### Indication Requirements

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 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.

### 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



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Pack Size/Poison information	
Pack Size	Poison Schedule
Components	
1 . Formulation 1	
Dosage Form	Powder
Route of Administration	Oral
Visual Identification	
Active Ingredients	
ascorbic acid	9.38 mg/g
hydrolysed collagen	937.5 mg/g
Other Ingredients (Excipients)	
colloidal anhydrous silica	
Flavour	
glycine	
Siraitia grosvenorii	
Stevia rebaudiana	

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