



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	318246	Qsilica Ceramosides + Antioxidant Pro Collagen One-A-Day Capsules
ARTG entry for	Medicine Listed	
Sponsor	Planet Health Pty Ltd	
Postal Address	42 Bowral Street, BOWRAL, NSW, 2576 Australia	
ARTG Start Date	3/06/2019	
Product Category	Medicine	
Status	Active	
Approval Area	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 . Qsilica Ceramosides + Antioxidant Pro Collagen One-A-Day Capsules

Product Type	Single Medicine Product	Effective Date	3/06/2019
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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
- Maintain/support collagen 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 bone health
- Maintain/support bone mass/density/integrity
- Help maintain/support bone mineralisation
- Helps maintain/supports healthy joint cartilage growth/development/production
- Maintain/support immune system health
- Maintain/support healthy immune system function
- Maintain/support healthy ligaments
- Maintain/support tendon health
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
- Maintain/support skin health

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Maintain/support skin integrity/structure
 Maintain/support wound healing

Indication Requirements

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.

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

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 serious immunological diseases.

Product presentation must not imply or refer to any form of arthritis or osteoarthritis unless qualified as mild.

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

Components

1 . Formulation 1

Dosage Form Capsule, hard
Route of Administration Oral

Visual Identification

Active Ingredients

calcium ascorbate dihydrate	49.67 mg
Equivalent: ascorbic acid	45 mg
colloidal anhydrous silica	130 mg
Equivalent: silicon	60 mg
Malpighia glabra fruit Extract dry concentrate	50 mg
Equivalent: Malpighia glabra (Dry)	500 mg
Triticum aestivum	30 mg

Other Ingredients (Excipients)

Acacia
disodium edetate
gellan gum
hypromellose
maltodextrin
Oryza sativa
potable water
potassium acetate
Sunflower Oil

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