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.

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 19/04/2023

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

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: [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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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.

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

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 seed endosperm Extract dry concentrate	30 mg
Equivalent: Triticum aestivum (Dry)	20010 mg

Other Ingredients (Excipients)

Acacia

disodium edetate

gellan gum

hypromellose

maltodextrin

Oryza sativa

potable water

potassium acetate

Sunflower Oil

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