# **Australian Government**

## **Department of Health**

# Therapeutic Goods Administration

### **Public Summary**

Summary for ARTG Entry: 358490 Anthogenol

ARTG entry for Medicine Listed

**Sponsor** Phytologic Holdings Pty Limited

Postal Address 16-20 Baker Street, Banksmeadow, NSW, 2019

Australia

ARTG Start Date 31/03/2021

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 . Anthogenol

Product Type Single Medicine Product Effective Date 10/05/2022

# Permitted Indications

Antioxidant/Reduce free radicals formed in the body

Maintain/support collagen formation

Maintain/support eye health

Aids/assists eye adaption to variations in light intensity/night vision

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

Aids/assists healthy bone development/growth/building

Help maintain/support bone mineralisation

Helps maintain/supports healthy joint cartilage growth/development/production

Maintain/support blood circulation/flow to the peripheral areas of the body (legs, hands and feet)

Maintain/support cardiovascular system health

Maintain/support blood capillary health

Maintain/support blood vessel health

Decrease/reduce/relieve symptoms of mild varicose veins

Maintain/support immune system health

Maintain/support healthy immune system function

Maintain/support tendon health

Maintain/support absorption of dietary (state vitamin/mineral/nutrient)

Maintain/support skin health

Maintain/support skin integrity/structure

### Indication Requirements

Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.

Page 1 of 2

Produced at 28.06.2022 at 03:35:05 AEST



# **Australian Government**

## **Department of Health**

## Therapeutic Goods Administration

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 vision correction, faults or serious eye disease e.g. macular degeneration.

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

Product presentation must not imply or refer to circulatory disorders/diseases/conditions e.g. thrombosis.

Product presentation must only refer to mild varicose veins.

Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.

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

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 cardiovascular conditions.

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

### **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** 

ascorbic acid40 mgsilicon dioxide20 mgVitis vinifera seed Extract dry concentrate100 mgEquivalent: Vitis vinifera (Dry)12000 mg

### Other Ingredients (Excipients)

hypromellose

magnesium stearate

microcrystalline cellulose

purified water

silicon dioxide

sorbitol

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at http://www.tga.gov.au/about/website-copyright.htm.