

# Australian Government

### **Department of Health**

# Therapeutic Goods Administration

### **Public Summary**

Summary for ARTG Entry: 335450 NUTRA-LIFE KYOLIC AGED GARLIC EXTRACT HEART & CHOLESTEROL FORMULA

ARTG entry for Medicine Listed

Sponsor Vitaco Health Australia Pty Ltd

Postal Address PO Box 399, NORTH RYDE BC, NSW, 1670

Australia

ARTG Start Date 30/04/2020
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.

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 . NUTRA-LIFE KYOLIC AGED GARLIC EXTRACT HEART & CHOLESTEROL FORMULA

Product Type Single Medicine Product Effective Date 30/04/2020

### **Permitted Indications**

Maintain/support energy production

Maintain/support general health and wellbeing

Helps maintain/support healthy cholesterol in healthy individuals

Helps maintain/support healthy blood sugar/glucose in healthy individuals

Maintain/support heart health

Maintain/support muscle function

Aid/assist/helps glucose/sugar/carbohydrate metabolism

Helps prevent dietary (state vitamin/mineral/nutrient) deficiency

Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)

Maintain/support nerve conduction

Aid/assist/helps synthesis of neurotransmitters

Maintain/support nervous system function

### **Indication Requirements**

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.

Product presentation must not imply or refer to serious cardiovascular conditions.

Product presentation must not imply or refer to mental illnesses, disorders or conditions.

Product presentation must not imply or refer to lowering or raising blood sugar/glucose levels from outside of the normal healthy range.

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).

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Product presentation must not imply or refer to lowering or raising blood cholesterol levels from outside of the normal healthy range

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**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** 

Allium sativum bulb Extract dry concentrate

Equivalent: Allium sativum (Fresh) 756 mg

chromium picolinate 70.12 microgram Equivalent: chromium 8.75 microgram thiamine hydrochloride 381.14 microgram Equivalent: thiamine 300 microgram

Other Ingredients (Excipients)

carmellose calcium

hypromellose

magnesium stearate

microcrystalline cellulose

powdered cellulose

purified water

silicon dioxide

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