

Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 261294 Thompson's Biotin 150mcg

ARTG entry for Medicine Listed

Sponsor Homart Wellness Aust Pty Ltd

Postal Address 59 Kirby Street, Rydalmere, NSW, 2116

Australia

ARTG Start Date 16/10/2015
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 . Thompson's Biotin 150mcg

Product Type Single Medicine Product Effective Date 12/05/2025

Permitted Indications

Maintain/support energy levels

Helps convert (state food) into energy

Maintain/support general health and wellbeing

Maintain/support general health and wellbeing in teenagers

Maintain/support general health and wellbeing in adults

Maintain/support general health and wellbeing in adolescents

Aid/assist/helps glucose/sugar/carbohydrate metabolism

Maintain/support (state vitamin/mineral/nutrient) levels in the body

Maintain/support (state vitamin/mineral/nutrient) levels in the body in adolescents

Maintain/support (state vitamin/mineral/nutrient) levels in the body in teenagers

Maintain/support (state vitamin/mineral) within normal range in teenagers

Maintain/support (state vitamin/mineral) within normal range in adults

Maintain/support (state vitamin/mineral) within normal range in adolescents

Maintain/support (state vitamin/mineral) within normal range

Indication Requirements

Product presentation must not imply or refer to chronic fatigue syndrome.

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

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).

Label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

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Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.

Additional Product information

Pack Size/Poison information

Pack Size Poison Schedule

Components

1 . Formulation 1

Dosage Form Tablet, uncoated

Route of Administration Oral

Visual Identification

Active Ingredients

Biotin 150 microgram

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate

magnesium stearate

microcrystalline cellulose

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