

#### **Australian Government**

## Department of Health, Disability and Ageing

Therapeutic Goods Administration

**Public Summary** 

Summary for ARTG Entry: 332240 High Potency Super Lecithin

ARTG entry for Medicine Listed

Sponsor Homart Wellness Aust Pty Ltd

Postal Address 59 Kirby Street, Rydalmere, NSW, 2116

Australia

ARTG Start Date 24/03/2020
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.

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 . High Potency Super Lecithin

Product Type Single Medicine Product Effective Date 7/10/2025

## Permitted Indications

Maintain/support general health and wellbeing

Aid/assist fat emulsification in the digestive system

Aid/assist/helps synthesis of neurotransmitters

### **Indication Requirements**

Product presentation must not imply or refer to lowering blood lipids, blood fats and triglycerides.

### **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, soft

Route of Administration Oral

Visual Identification

**Active Ingredients** 

lecithin 1.2 g

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## Other Ingredients (Excipients)

fractionated coconut oil

Gelatin
glycerol
purified water
sorbitol solution (70 per cent) (non-crystallising)

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