Public Summary

Summary for ARTG Entry:	400325 NICOTINAMIDE RIBOSIDE LIPOSOMAL
ARTG entry for	Medicine Listed
Sponsor	Melrose Laboratories Pty Ltd
Postal Address	16-18 Lionel Rd, Mt Waverley, VIC, 3149 Australia
ARTG Start Date	29/11/2022
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 . NICOTINAMIDE RIBOSIDE LIPOSOMAL

Product Type Single Medicine Product **Effective Date** 8/12/2022

Permitted Indications

Maintain/support energy levels

Maintain/support general health and wellbeing

Indication Requirements

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

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Not to be taken by children under 12 years old (or words to that effect).

Contains ethanol or contains alcohol.

(If medicine contains one sugar) contains [insert name of sugar] OR (If medicine contains two or more sugars) Contains sugars [or words to that effect].

Additional Product information

Pack Size/Poison information

Pack Size **Poison Schedule**

Components

1 . Formulation 1

Dosage Form	Oral Liquid
Route of Administration	Oral
Visual Identification	

Active Ingredients

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nicotinamide riboside chloride	**55.6 mg/g**
Equivalent: ribose	25.5 mg/g

Other Ingredients (Excipients)

ethanol
Flavour
glycerol
lecithin
purified water
sucralose
tocofersolan

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