Public Summary

Summary for ARTG Entry:	338266 Lipotropex
ARTG entry for	Medicine Listed
Sponsor	RN Labs Pty Ltd
Postal Address	18 / 93 Rivergate Place, MURARRIE, QLD, 4172 Australia
ARTG Start Date	23/06/2020
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 . Lipotropex

Product Type Single Medicine Product **Effective Date** 23/06/2020

Permitted Indications

Maintain/support natural liver cleansing/detoxification processes

Aid/assist/helps digestion of fats/fatty acids/triglycerides/lipid

Maintain/support bile production

Maintain/support healthy liver function

Indication Requirements

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

Product presentation must only refer to detoxification in relation to natural body processes.

Product presentation must not imply or refer to drugs/alcohol.

Product presentation must not imply or refer to liver disease, such as cirrhosis, hepatitis.

Product presentation must not imply or refer to disease in any body organ, in particular the kidney or liver.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

This medicine contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.

Additional Product information

Pack Size/Poison information

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Pack Size **Poison Schedule**

Components

1 . Formulation 1

Dosage Form	Powder
Route of Administration	Oral
Visual Identification	

Active Ingredients

acetyl levocarnitine hydrochloride	**116.67 mg/g**
ascorbic acid	**41.67 mg/g**
choline bitartrate	**83.33 mg/g**
glycine	**150 mg/g**
inositol	**116.67 mg/g**
selenomethionine	**.0124 mg/g**
Equivalent: selenium	.005 mg/g
Silybum marianum fruit Extract dry concentrate	**83.33 mg/g**
Equivalent: Silybum marianum (Dry)	5.83 g/g
taurine	**166.67 mg/g**

Other Ingredients (Excipients)

colloidal anhydrous silica
Flavour
glycine
Siraitia grosvenorii
Stevia rebaudiana

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