



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	357850	UltraLiv
ARTG entry for	Medicine Listed	
Sponsor	Biomedica Nutraceuticals Pty Ltd	
Postal Address	PO Box 7052, ALEXANDRIA, NSW, 2015 Australia	
ARTG Start Date	26/03/2021	
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 . UltraLiv

Product Type	Single Medicine Product	Effective Date	26/03/2021
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Permitted Indications

Antioxidant/Reduce free radicals formed in the body
Helps reduce/decrease free radical damage to body cells
Maintain/support general health and wellbeing
Traditionally used in Western herbal medicine to hepatoprotectant/protect the liver
Hepatoprotectant/protect the liver
Maintain/support healthy liver function
Maintain/support liver health
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
Maintain/support (state vitamin/mineral) within normal range

Indication Requirements

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).
Product presentation must not imply or refer to liver disease, such as cirrhosis, hepatitis.
Product presentation must not encourage excessive or harmful consumption of alcohol or other toxic substances.

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
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Components

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

calcium folinate	108.5 microgram
Equivalent: folic acid	100 microgram
choline bitartrate	150 mg
cyanocobalamin	100 microgram
folic acid	99 microgram
inositol	100 mg
methionine	50 mg
Peppermint Oil	4 mg
pyridoxal 5-phosphate monohydrate	4.02 mg
Equivalent: pyridoxine	2.75 mg
pyridoxine hydrochloride	3.34 mg
Equivalent: pyridoxine	2.75 mg
Silybum marianum seed Extract dry concentrate	171.43 mg
Equivalent: Silybum marianum (Dry)	12 g
Taraxacum officinale root Extract dry concentrate	50 mg
Equivalent: Taraxacum officinale (Dry)	200 mg
taurine	100 mg

Other Ingredients (Excipients)

calcium hydrogen phosphate
colloidal anhydrous silica
hypromellose
maltodextrin
microcrystalline cellulose
mono- and di- glycerides
Peppermint Oil
purified water
silicon dioxide
stearic acid

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