Public Summary

Summary for ARTG Entry:	277599 Neuro Opti-B
ARTG entry for	Medicine Listed
Sponsor	MD Nutritionals
Postal Address	21D/5 Bayview Street, Runaway Bay, QLD, 4216 Australia
ARTG Start Date	8/07/2016
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.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

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 . Neuro Opti-B

Product Type	Single Medicine Product	**Effective Date**	2/08/2019

Permitted Indications

Enhance/promote energy levels

Helps decrease/reduce homocysteine levels

Help maintain/support emotional wellbeing

Decrease/reduce/relieve symptoms of stress

Decrease/reduce/relieve symptoms of mild anxiety

Maintain/support mental concentration/focus/clarity

Enhance/improve/promote/increase cognitive performance

Maintain/support cognitive function/mental function

Aid/assist/helps synthesis of neurotransmitters

Maintain/support nervous system function

Support healthy emotional/mood balance

Indication Requirements

Product presentation must not imply or refer to mental illnesses, disorders or conditions.

Label statement: If symptoms persist, talk to your health professional.

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

Product presentation must only refer to mild anxiety.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

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

If symptoms persist consult your healthcare practitioner (or words to that effect).

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Multiple containers	Not recorded	Not recorded	Not recorded	Not recorded	Not recorded

Pack Size/Poison information

Pack Size	Poison Schedule

Components

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

Biotin	**30 microgram**
calcium folinate	**432.15 microgram**
Equivalent: folinic acid	400 microgram
calcium pantothenate	**100 mg**
Equivalent: pantothenic acid	91.6 mg
choline bitartrate	**50 mg**
inositol	**50 mg**
mecobalamin (co-methylcobalamin)	**200 microgram**
nicotinamide	**100 mg**
pyridoxal 5-phosphate	**25 mg**
Equivalent: pyridoxine	17.11 mg
riboflavin sodium phosphate	**30 mg**
thiamine hydrochloride	**50 mg**

Other Ingredients (Excipients)

colloidal anhydrous silica
disodium edetate
gellan gum
hypromellose
magnesium stearate
microcrystalline cellulose
potable water
potassium acetate

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