

Australian Government

Department of Health, Disability and Ageing

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 329112 NanoCelle Activated B12

ARTG entry for Medicine Listed

Sponsor Natural Bio Pty Limited

Postal Address PO Box 384, MONA VALE, NSW, 1660

Australia

ARTG Start Date 23/01/2020
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 . NanoCelle Activated B12

Product Type Single Medicine Product Effective Date 4/09/2025

Permitted Indications

Maintain/support energy production

Relieve weariness/tiredness/fatigue/feeling of weakness

Aid/assist healthy red blood cell production

Helps decrease/reduce homocysteine levels

Enhance/improve/promote/increase (state vitamin/mineral/nutrient) levels in the body

Helps prevent dietary (state vitamin/mineral/nutrient) deficiency

Maintain/support nervous system function

Indication Requirements

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

If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.

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

Product presentation must not imply or refer to serious cardiovascular conditions.

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

If product is indicated for supplementation, 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).

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).

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

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

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

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Not recorded

Not recorded

Therapeutic Goods Administration

Contains sorbates

Additional Product information

Container information					
Туре	Material	Life Time	Temperature	Closure	Conditions

Pack Size/Poison information

Not recorded

Pack Size Poison Schedule

Not recorded

Components

1 . Formulation 1

Multiple containers

Dosage FormSprayRoute of AdministrationOral

Visual Identification

Active Ingredients

mecobalamin 3.33 mg/mL

Other Ingredients (Excipients)

citric acid

d-alpha-tocopherol

glycerol

PEG-40 hydrogenated castor oil

Peppermint Oil

potassium sorbate

purified water

Steviol glycosides

Sunflower Oil

Not recorded

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