



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	297676	Eagle Sublingual B12 1000
ARTG entry for	Medicine Listed	
Sponsor	Integria Healthcare Australia Pty Ltd	
Postal Address	PO Box 4854, EIGHT MILE PLAINS, QLD, 4113 Australia	
ARTG Start Date	18/12/2017	
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 . Eagle Sublingual B12 1000

Product Type	Single Medicine Product	Effective Date	29/01/2021
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Permitted Indications

Helps convert (state food) into energy
Maintain/support energy production
Maintain/support general health and wellbeing
Aid/assist healthy red blood cell production
Maintain/support red blood cell health
Aid/assist/helps glucose/sugar/carbohydrate metabolism
Maintain/support (state vitamin/mineral/nutrient) levels in the body
Maintain/support (state vitamin/mineral/nutrient) levels in the body in elderly individuals
Maintain/support (state vitamin/mineral/nutrient) levels in the body In older females
Maintain/support (state vitamin/mineral/nutrient) levels in the body In older males
Maintain/support (state vitamin/mineral/nutrient) levels in the body in vegetarians
Maintain/support (state vitamin/mineral/nutrient) levels in the body in vegans
Maintain/support (state vitamin/mineral/nutrient) levels in the body in adolescents
Maintain/support (state vitamin/mineral) within normal range in elderly individuals
Maintain/support (state vitamin/mineral) within normal range
Maintain/support (state vitamin/mineral) within normal range in adolescents
Maintain/support (state vitamin/mineral) within normal range In older males
Maintain/support (state vitamin/mineral) within normal range In older females
Maintain/support (state vitamin/mineral) within normal range in vegetarians
Maintain/support (state vitamin/mineral) within normal range in vegans
Maintain/support nerve conduction

Indication Requirements

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.

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

Product presentation must not imply or refer to lowering or raising blood sugar/glucose levels from outside of the normal healthy range.

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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).

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

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.

For practitioner dispensing only.

If symptoms persist, seek the advice of a healthcare professional.

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form Tablet, uncoated

Route of Administration Oral

Visual Identification

Active Ingredients

cyanocobalamin	1 mg
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Other Ingredients (Excipients)

citric acid

colloidal anhydrous silica

croscarmellose sodium

crospovidone

Flavour

magnesium stearate

mannitol

microcrystalline cellulose

sodium bicarbonate

sorbitol

xylitol

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