



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	337233	Liquid Multivitamin for Infants
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	BNutrition Pty Ltd	
<b>Postal Address</b>	PO Box 234, Tanunda, SA, 5352 Australia	
<b>ARTG Start Date</b>	29/05/2020	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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 . Liquid Multivitamin for Infants

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	30/07/2022
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### Permitted Indications

Antioxidant/Reduce free radicals formed in the body in healthy infants  
Maintain/support collagen formation in healthy infants  
Maintain/support energy levels in healthy infants  
Helps convert (state food) into energy in healthy infants  
Maintain/support energy production in healthy infants  
Maintain/support healthy eye function in healthy infants  
Maintain/support eye health in healthy infants  
Maintain/support healthy eyesight/vision in healthy infants  
Maintain/support healthy growth and development in healthy infants  
Maintain/support body mucous membrane health in healthy infants  
Maintain/support general health and wellbeing in healthy infants  
Maintain/support hair health in healthy infants  
Aids/assists teeth development in healthy infants  
Maintain/support healthy teeth in healthy infants  
Maintain/support nail health/strength/thickness in healthy infants  
Maintain/support connective tissue health in healthy infants  
Aid/assist/helps connective tissue production/formation in healthy infants  
Maintain/support bone health in healthy infants  
Aids/assists healthy bone development/growth/building in healthy infants  
Help maintain/support bone mineralisation in healthy infants  
Aid/assist healthy red blood cell production in healthy infants  
Maintain/support red blood cell health in healthy infants  
Maintain/support blood health in healthy infants  
Helps maintain/support haemoglobin formation/synthesis in healthy infants  
Maintain/support healthy liver function in healthy infants  
Maintain/support immune system health in healthy infants  
Maintain/support healthy immune system function in healthy infants



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Maintain/support muscle function in healthy infants  
Aid/assist/helps protein synthesis in the body in healthy infants  
Maintain/support absorption of dietary (state vitamin/mineral/nutrient) in healthy infants  
Maintain/support (state vitamin/mineral/nutrient) levels in the body in breast fed healthy infants  
Maintain/support (state vitamin/mineral/nutrient) levels in the body in healthy infants  
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency in breast fed healthy infants  
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency in healthy infants  
Aid/assist/helps metabolism of (state vitamin/mineral/nutrient) in healthy infants  
Maintain/support cognitive development in healthy infants  
Maintain/support nerve conduction in healthy infants  
Aid/assist/helps synthesis of neurotransmitters in healthy infants  
Maintain/support nervous system health in healthy infants  
Maintain/support nervous system function in healthy infants  
Maintain/support skin health in healthy infants  
Maintain/support skin integrity/structure  
Maintain/support wound healing in healthy infants  
Antioxidant/Reduce free radicals formed in the body in healthy infants  
Maintain/support collagen formation in healthy infants  
Maintain/support energy levels in healthy infants  
Helps convert (state food) into energy in healthy infants  
Maintain/support energy production in healthy infants  
Maintain/support healthy eye function in healthy infants  
Maintain/support eye health in healthy infants  
Maintain/support healthy eyesight/vision in healthy infants  
Maintain/support healthy growth and development in healthy infants  
Maintain/support body mucous membrane health in healthy infants  
Maintain/support general health and wellbeing in healthy infants  
Maintain/support hair health in healthy infants  
Aids/assists teeth development in healthy infants  
Maintain/support healthy teeth in healthy infants  
Maintain/support nail health/strength/thickness in healthy infants  
Maintain/support connective tissue health in healthy infants  
Aid/assist/helps connective tissue production/formation in healthy infants  
Maintain/support bone health in healthy infants  
Aids/assists healthy bone development/growth/building in healthy infants  
Help maintain/support bone mineralisation in healthy infants  
Aid/assist healthy red blood cell production in healthy infants  
Maintain/support red blood cell health in healthy infants  
Maintain/support blood health in healthy infants  
Helps maintain/support haemoglobin formation/synthesis in healthy infants  
Maintain/support healthy liver function in healthy infants  
Maintain/support immune system health in healthy infants  
Maintain/support healthy immune system function in healthy infants  
Maintain/support muscle function in healthy infants  
Aid/assist/helps protein synthesis in the body in healthy infants  
Maintain/support absorption of dietary (state vitamin/mineral/nutrient) in healthy infants  
Maintain/support (state vitamin/mineral/nutrient) levels in the body in healthy infants  
Maintain/support (state vitamin/mineral/nutrient) levels in the body in breast fed healthy infants  
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency in breast fed healthy infants  
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency in healthy infants  
Aid/assist/helps metabolism of (state vitamin/mineral/nutrient) in healthy infants  
Maintain/support cognitive development in healthy infants  
Maintain/support nerve conduction in healthy infants  
Aid/assist/helps synthesis of neurotransmitters in healthy infants  
Maintain/support nervous system health in healthy infants



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Maintain/support nervous system function in healthy infants  
Maintain/support skin health in healthy infants  
Maintain/support skin integrity/structure  
Maintain/support wound healing in healthy infants

#### 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 neurological conditions or developmental delays.  
Product presentation must not imply or refer to mental illnesses, disorders or conditions.  
Product presentation must not imply or refer to chronic fatigue syndrome.  
Label statement: If symptoms persist, talk to your health professional.  
Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.  
Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.  
Product presentation must not imply or refer to serious cardiovascular conditions.  
Product presentation must not imply or refer to serious immunological diseases.  
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.  
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: 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 liver disease, such as cirrhosis, hepatitis.

#### Standard Indications

No Standard Indications included on Record

#### Specific Indications

No Specific Indications included on Record

#### Warnings

Contains sorbates' (or word to this effect) if medicine contains two or more sorbate sources OR 'Contains [insert the approved name of sorbate source used]' (or words to this effect) if medicine contains one sorbate source.

#### Additional Product information

#### Pack Size/Poison information

<b>Pack Size</b>	<b>Poison Schedule</b>
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#### Components

##### 1 . Formulation 1

**Dosage Form** Oral Liquid

**Route of Administration** Oral

#### Visual Identification

#### Active Ingredients

<b>betacarotene</b>	<b>3 mg/mL</b>
<b>Biotin</b>	<b>1.5 microgram/mL</b>
<b>calcium ascorbate dihydrate</b>	<b>9.12 mg/mL</b>
Equivalent: calcium	860 microgram/mL
Equivalent: ascorbic acid	7.5 mg/mL
<b>choline bitartrate</b>	<b>91.91 mg/mL</b>
Equivalent: choline	37.5 mg/mL
<b>colecalfiferol</b>	<b>5 microgram/mL</b>
<b>cyanocobalamin</b>	<b>.417 microgram/mL</b>
<b>d-alpha-tocopheryl acetate</b>	<b>4.04 mg/mL</b>
<b>levomefolate glucosamine</b>	<b>144.27 microgram/mL</b>
Equivalent: levomefolic acid	80 microgram/mL

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<b>nicotinamide</b>	<b>1 mg/mL</b>
<b>pyridoxal 5-phosphate monohydrate</b>	<b>177 microgram/mL</b>
Equivalent: pyridoxine	100 microgram/mL
<b>riboflavin sodium phosphate</b>	<b>195 microgram/mL</b>
Equivalent: riboflavin	150 microgram/mL
<b>thiamine hydrochloride</b>	<b>112 microgram/mL</b>
Equivalent: thiamine	100 microgram/mL

#### Other Ingredients (Excipients)

ascorbyl palmitate  
dl-alpha-tocopherol  
Gelatin  
glycerol  
Maize Oil  
maize starch  
potassium sorbate  
purified water  
sucrose  
vegetable oil  
xanthan gum

## 2 . Liquid Multivitamin for Infants

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	30/07/2022
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#### Permitted Indications

Antioxidant/Reduce free radicals formed in the body in healthy infants  
Maintain/support collagen formation in healthy infants  
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Helps convert (state food) into energy in healthy infants  
Maintain/support energy production in healthy infants  
Maintain/support healthy eye function in healthy infants  
Maintain/support eye health in healthy infants  
Maintain/support healthy eyesight/vision in healthy infants  
Maintain/support healthy growth and development in healthy infants  
Maintain/support body mucous membrane health in healthy infants  
Maintain/support general health and wellbeing in healthy infants  
Maintain/support hair health in healthy infants  
Aids/assists teeth development in healthy infants  
Maintain/support healthy teeth in healthy infants  
Maintain/support nail health/strength/thickness in healthy infants  
Maintain/support connective tissue health in healthy infants  
Aid/assist/helps connective tissue production/formation in healthy infants  
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Help maintain/support bone mineralisation in healthy infants  
Aid/assist healthy red blood cell production in healthy infants  
Maintain/support red blood cell health in healthy infants  
Maintain/support blood health in healthy infants  
Helps maintain/support haemoglobin formation/synthesis in healthy infants  
Maintain/support healthy liver function in healthy infants  
Maintain/support immune system health in healthy infants  
Maintain/support healthy immune system function in healthy infants  
Maintain/support muscle function in healthy infants  
Aid/assist/helps protein synthesis in the body in healthy infants



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Maintain/support absorption of dietary (state vitamin/mineral/nutrient) in healthy infants  
Maintain/support (state vitamin/mineral/nutrient) levels in the body in breast fed healthy infants  
Maintain/support (state vitamin/mineral/nutrient) levels in the body in healthy infants  
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency in breast fed healthy infants  
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency in healthy infants  
Aid/assist/helps metabolism of (state vitamin/mineral/nutrient) in healthy infants  
Maintain/support cognitive development in healthy infants  
Maintain/support nerve conduction in healthy infants  
Aid/assist/helps synthesis of neurotransmitters in healthy infants  
Maintain/support nervous system health in healthy infants  
Maintain/support nervous system function in healthy infants  
Maintain/support skin health in healthy infants  
Maintain/support skin integrity/structure  
Maintain/support wound healing in healthy infants  
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Maintain/support nerve conduction in healthy infants  
Aid/assist/helps synthesis of neurotransmitters in healthy infants  
Maintain/support nervous system health in healthy infants  
Maintain/support nervous system function in healthy infants  
Maintain/support skin health in healthy infants



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Maintain/support skin integrity/structure  
Maintain/support wound healing in healthy infants

#### Indication Requirements

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

Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.  
Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.

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

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

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).

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Product presentation must not imply or refer to neurological conditions or developmental delays.

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

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: 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 immunological diseases.

#### Standard Indications

No Standard Indications included on Record

#### Specific Indications

No Specific Indications included on Record

#### Warnings

Contains sorbates' (or word to this effect) if medicine contains two or more sorbate sources OR 'Contains [insert the approved name of sorbate source used]' (or words to this effect) if medicine contains one sorbate source.

#### Additional Product information

#### Pack Size/Poison information

##### Pack Size

##### Poison Schedule

#### Components

##### 1 . Formulation 1

**Dosage Form** Oral Liquid

**Route of Administration** Oral

##### Visual Identification

##### Active Ingredients

<b>betacarotene</b>	<b>3 mg/mL</b>
<b>Biotin</b>	<b>1.5 microgram/mL</b>
<b>calcium ascorbate dihydrate</b>	<b>9.12 mg/mL</b>
Equivalent: calcium	860 microgram/mL
Equivalent: ascorbic acid	7.5 mg/mL
<b>choline bitartrate</b>	<b>91.91 mg/mL</b>
Equivalent: choline	37.5 mg/mL
<b>colecalfiferol</b>	<b>5 microgram/mL</b>
<b>cyanocobalamin</b>	<b>.417 microgram/mL</b>
<b>d-alpha-tocopheryl acetate</b>	<b>4.04 mg/mL</b>
<b>levomefolate glucosamine</b>	<b>144.27 microgram/mL</b>
Equivalent: levomefolic acid	80 microgram/mL
<b>nicotinamide</b>	<b>1 mg/mL</b>
<b>pyridoxal 5-phosphate monohydrate</b>	<b>177 microgram/mL</b>



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Equivalent: pyridoxine	100 microgram/mL
<b>riboflavin sodium phosphate</b>	<b>195 microgram/mL</b>
Equivalent: riboflavin	150 microgram/mL
<b>thiamine hydrochloride</b>	<b>112 microgram/mL</b>
Equivalent: thiamine	100 microgram/mL

**Other Ingredients (Excipients)**

ascorbyl palmitate  
dl-alpha-tocopherol  
Gelatin  
glycerol  
Maize Oil  
maize starch  
potassium sorbate  
purified water  
sucrose  
vegetable oil  
xanthan gum

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