



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

**Public Summary**

|                                |                                            |                               |
|--------------------------------|--------------------------------------------|-------------------------------|
| <b>Summary for ARTG Entry:</b> | 330611                                     | Liquid Multivitamin with iron |
| <b>ARTG entry for</b>          | Medicine Listed                            |                               |
| <b>Sponsor</b>                 | BNutrition Pty Ltd                         |                               |
| <b>Postal Address</b>          | PO Box 234, Tanunda, SA, 5352<br>Australia |                               |
| <b>ARTG Start Date</b>         | 2/03/2020                                  |                               |
| <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.

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.

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 . Liquid Multivitamin with iron**

|                     |                         |                       |           |
|---------------------|-------------------------|-----------------------|-----------|
| <b>Product Type</b> | Single Medicine Product | <b>Effective Date</b> | 7/04/2020 |
|---------------------|-------------------------|-----------------------|-----------|

**Permitted Indications**

- Antioxidant/Reduce free radicals formed in the body in children
- Antioxidant/Reduce free radicals formed in the body in teenagers
- Helps reduce/decrease free radical damage to body cells in teenagers
- Helps reduce/decrease free radical damage to body cells in children
- Maintain/support collagen formation in teenagers
- Maintain/support collagen formation in children
- Maintain/support energy levels in teenagers
- Maintain/support energy levels in children
- Helps convert (state food) into energy in teenagers
- Helps convert (state food) into energy in children
- Maintain/support body metabolism/metabolic rate in teenagers
- Maintain/support energy production in teenagers
- Maintain/support energy production in children
- Maintain/support heat/energy production/thermogenesis in teenagers
- Maintain/support healthy eye function in children
- Maintain/support healthy eye function in teenagers
- Maintain/support eye health in children
- Maintain/support eye health in teenagers
- Maintain/support healthy eyesight/vision in teenagers
- Maintain/support healthy eyesight/vision in children
- Maintain/support healthy growth and development in children
- Maintain/support general health and wellbeing in teenagers
- Maintain/support general health and wellbeing in children

Public Summary



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

Public Summary

Aids/assists teeth development in children  
Maintain/support healthy teeth in children  
Maintain/support healthy teeth in teenagers  
Maintain/support teeth mineralisation in children  
Maintain/support connective tissue health in children  
Maintain/support connective tissue health in teenagers  
Aid/assist/helps connective tissue production/formation in teenagers  
Aid/assist/helps connective tissue production/formation in children  
Maintain/support healthy body tissues in teenagers  
Maintain/support bone health in teenagers  
Maintain/support bone health in children  
Aids/assists healthy bone development/growth/building in children  
Aids/assists healthy bone development/growth/building in teenagers  
Maintain/support bone strength in teenagers  
Maintain/support bone strength in children  
Help maintain/support bone mineralisation in children  
Help maintain/support bone mineralisation in teenagers  
Aid/assist healthy red blood cell production in children  
Aid/assist healthy red blood cell production in teenagers  
Maintain/support red blood cell health in teenagers  
Maintain/support red blood cell health in children  
Maintain/support blood health in teenagers  
Maintain/support blood health in children  
Helps maintain/support transport of oxygen in the body in teenagers  
Helps maintain/support transport of oxygen in the body in children  
Aid/assist/helps oxygen transport to body tissues in teenagers  
Aid/assist/helps oxygen transport to body tissues in children  
Helps maintain/support haemoglobin formation/synthesis in children  
Helps maintain/support haemoglobin formation/synthesis in teenagers  
Maintain/support immune system health in teenagers  
Maintain/support immune system health in children  
Maintain/support healthy immune system function in children  
Maintain/support healthy immune system function in teenagers  
Maintain/support muscle function in teenagers  
Maintain/support muscle function in children  
Maintain/support healthy neuromuscular system/function in children  
Maintain/support healthy neuromuscular system/function in teenagers  
Aid/assist/helps glucose/sugar/carbohydrate metabolism in teenagers  
Aid/assist/helps glucose/sugar/carbohydrate metabolism in children  
Aid/assist/helps protein synthesis in the body in teenagers  
Aid/assist/helps protein synthesis in the body in children  
Maintain/support absorption of dietary (state vitamin/mineral/nutrient) in children  
Maintain/support absorption of dietary (state vitamin/mineral/nutrient) in teenagers  
Maintain/support (state vitamin/mineral/nutrient) levels in the body in teenagers  
Maintain/support (state vitamin/mineral/nutrient) levels in the body in children  
Maintain/support (state vitamin/mineral/nutrient) levels in the body when sun exposure is inadequate in children  
Maintain/support (state vitamin/mineral/nutrient) levels in the body when sun exposure is inadequate in teenagers  
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency in children  
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency in teenagers  
Aid/assist/helps metabolism of (state vitamin/mineral/nutrient) in teenagers  
Aid/assist/helps metabolism of (state vitamin/mineral/nutrient) in children  
Maintain/support cognitive development in children  
Maintain/support cognitive function/mental function in teenagers  
Maintain/support cognitive function/mental function in children  
Maintain/support nerve conduction in children



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

- Maintain/support nerve conduction in teenagers
- Aid/assist/helps synthesis of neurotransmitters in teenagers
- Aid/assist/helps synthesis of neurotransmitters in children
- Maintain/support nervous system health in children
- Maintain/support nervous system health in teenagers
- Maintain/support nervous system function in children
- Maintain/support nervous system function in teenagers
- Maintain/support skin health in children
- Maintain/support skin health in teenagers
- Maintain/support skin integrity/structure in teenagers
- Maintain/support skin integrity/structure in children
- Maintain/support skin regeneration in children
- Maintain/support skin regeneration in teenagers
- Maintain/support wound healing in teenagers
- Maintain/support wound healing in children

**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 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 heart disease.

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

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 mental illnesses, disorders or conditions.

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

Product presentation must not imply or refer to vision correction, faults or serious eye disease e.g. macular degeneration.

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

Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.

Product presentation must not imply or refer to serious immunological diseases.

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

Label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.

**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> |
|------------------|------------------------|

**Components**

**1 . Formulation 1**

|                                |             |
|--------------------------------|-------------|
| <b>Dosage Form</b>             | Oral Liquid |
| <b>Route of Administration</b> | Oral        |

**Visual Identification**

**Active Ingredients**

Public Summary



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

|                                               |                           |
|-----------------------------------------------|---------------------------|
| <b>betacarotene</b>                           | <b>1 mg/mL</b>            |
| <b>Biotin</b>                                 | <b>1.6 microgram/mL</b>   |
| <b>calcium ascorbate dihydrate</b>            | <b>3.41 mg/mL</b>         |
| Equivalent: ascorbic acid                     | 2.8 mg/mL                 |
| Equivalent: calcium                           | 320 microgram/mL          |
| <b>calcium phosphate</b>                      | <b>26.4325 mg/mL</b>      |
| <b>choline bitartrate</b>                     | <b>20 mg/mL</b>           |
| Equivalent: choline                           | 8.26 mg/mL                |
| <b>colecalfiferol</b>                         | <b>.5 microgram/mL</b>    |
| <b>d-alpha-tocopheryl acetate</b>             | <b>2 mg/mL</b>            |
| <b>dibasic magnesium phosphate trihydrate</b> | <b>24 mg/mL</b>           |
| Equivalent: magnesium                         | 3.3 mg/mL                 |
| <b>ferric pyrophosphate</b>                   | <b>3.325 mg/mL</b>        |
| <b>levomefolate glucosamine</b>               | <b>72.13 microgram/mL</b> |
| Equivalent: levomefolic acid                  | 40 microgram/mL           |
| <b>manganese amino acid chelate</b>           | <b>1 mg/mL</b>            |
| Equivalent: manganese                         | 200 microgram/mL          |
| <b>mecobalamin (co-methylcobalamin)</b>       | <b>.18 microgram/mL</b>   |
| <b>nicotinamide</b>                           | <b>400 microgram/mL</b>   |
| <b>potassium iodide</b>                       | <b>11.8 microgram/mL</b>  |
| Equivalent: iodine                            | 9 microgram/mL            |
| <b>pyridoxal 5-phosphate monohydrate</b>      | <b>176 microgram/mL</b>   |
| Equivalent: pyridoxine                        | 100 microgram/mL          |
| <b>riboflavin sodium phosphate</b>            | <b>80 microgram/mL</b>    |
| Equivalent: riboflavin                        | 60 microgram/mL           |
| <b>thiamine hydrochloride</b>                 | <b>89 microgram/mL</b>    |
| Equivalent: thiamine                          | 80 microgram/mL           |
| <b>zinc glycinate</b>                         | <b>4 mg/mL</b>            |
| Equivalent: zinc                              | 1.2 mg/mL                 |

**Other Ingredients (Excipients)**

ascorbyl palmitate  
citric acid  
dextrin  
dl-alpha-tocopherol  
Flavour  
Gelatin  
glycerol  
lecithin  
Maize Oil  
maize starch  
potassium sorbate  
purified water  
sodium chloride  
sucrose  
vegetable oil  
xanthan gum

Public Summary

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