



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	313393	Brauer Kids Liquid Iron with Vitamin B
<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>	18/01/2019	
<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 . Brauer Kids Liquid Iron with Vitamin B

Product Type	Effective Date
Single Medicine Product	30/07/2022

### Permitted Indications

- Maintain/support energy levels
- Maintain/support heat/energy production/thermogenesis
- Maintain/support healthy growth and development
- Maintain/support general health and wellbeing
- Aid/assist healthy red blood cell production
- Maintain/support blood health
- Helps maintain/support transport of oxygen in the body
- Aid/assist/helps oxygen transport to body tissues
- Helps maintain/support haemoglobin formation/synthesis
- Maintain/support immune system health
- Maintain/support healthy immune system function
- Aid/assist/helps protein synthesis in the body
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
- Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)
- Maintain/support cognitive development
- Aid/assist/helps synthesis of neurotransmitters
- Maintain/support nervous system health
- Maintain/support nervous system function
- Maintain/support energy levels
- Maintain/support heat/energy production/thermogenesis
- Maintain/support healthy growth and development
- Maintain/support general health and wellbeing
- Aid/assist healthy red blood cell production
- Maintain/support blood health
- Helps maintain/support transport of oxygen in the body
- Aid/assist/helps oxygen transport to body tissues
- Helps maintain/support haemoglobin formation/synthesis

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Maintain/support immune system health  
 Maintain/support healthy immune system function  
 Aid/assist/helps protein synthesis in the body  
 Helps prevent dietary (state vitamin/mineral/nutrient) deficiency  
 Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)  
 Maintain/support cognitive development  
 Aid/assist/helps synthesis of neurotransmitters  
 Maintain/support nervous system health  
 Maintain/support nervous system function

**Indication Requirements**

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 heart disease.  
 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 serious cardiovascular conditions.  
 Product presentation must not imply or refer to serious immunological diseases.  
 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.

**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.  
 Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.  
 Not for the treatment of iron deficiency conditions (or words to that effect).

**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>ferric pyrophosphate</b>	<b>3.325 mg/mL</b>
Equivalent: iron	1 mg/mL
<b>levomefolate glucosamine</b>	<b>27 microgram/mL</b>
Equivalent: levomefolic acid	15 microgram/mL
<b>mecobalamin</b>	<b>.09 microgram/mL</b>
<b>pyridoxal 5-phosphate monohydrate</b>	<b>88 microgram/mL</b>
Equivalent: pyridoxine	50 microgram/mL

**Other Ingredients (Excipients)**

**dextrin**  
**Flavour**  
**glycerol**  
**lecithin**

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potassium sorbate  
 purified water  
 sodium chloride  
 xanthan gum

**2 . Brauer Kids Liquid Iron with Vitamin B**

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

- Maintain/support energy levels
- Maintain/support heat/energy production/thermogenesis
- Maintain/support healthy growth and development
- Maintain/support general health and wellbeing
- Aid/assist healthy red blood cell production
- Maintain/support blood health
- Helps maintain/support transport of oxygen in the body
- Aid/assist/helps oxygen transport to body tissues
- Helps maintain/support haemoglobin formation/synthesis
- Maintain/support immune system health
- Maintain/support healthy immune system function
- Aid/assist/helps protein synthesis in the body
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
- Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)
- Maintain/support cognitive development
- Aid/assist/helps synthesis of neurotransmitters
- Maintain/support nervous system health
- Maintain/support nervous system function
- Maintain/support energy levels
- Maintain/support heat/energy production/thermogenesis
- Maintain/support healthy growth and development
- Maintain/support general health and wellbeing
- Aid/assist healthy red blood cell production
- Maintain/support blood health
- Helps maintain/support transport of oxygen in the body
- Aid/assist/helps oxygen transport to body tissues
- Helps maintain/support haemoglobin formation/synthesis
- Maintain/support immune system health
- Maintain/support healthy immune system function
- Aid/assist/helps protein synthesis in the body
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
- Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)
- Maintain/support cognitive development
- Aid/assist/helps synthesis of neurotransmitters
- Maintain/support nervous system health
- Maintain/support nervous system function

**Indication Requirements**

- Product presentation must not imply or refer to serious cardiovascular conditions.
- Product presentation must not imply or refer to chronic fatigue syndrome.
- Product presentation must not imply or refer to heart disease.
- Product presentation must not imply or refer to serious immunological diseases.
- 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.
- Label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.

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

**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.

Not for the treatment of iron deficiency conditions (or words to that effect).

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**

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<b>pyridoxal 5-phosphate monohydrate</b>	<b>88 microgram/mL</b>
Equivalent: pyridoxine	50 microgram/mL

**Other Ingredients (Excipients)**

- dextrin
- Flavour
- glycerol
- lecithin
- potassium sorbate
- purified water
- sodium chloride
- xanthan gum

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