



Australian Government

Department of Health, Disability and Ageing
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:		313393	Brauer Kids Liquid Iron with Vitamin B
ARTG entry for	Medicine Listed		
Sponsor	Brauer Nutrition Pty Ltd		
Postal Address	PO Box 234, Tanunda, SA, 5352 Australia		
ARTG Start Date	18/01/2019		
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 . Brauer Kids Liquid Iron with Vitamin B

Product Type	Single Medicine Product	Effective Date	3/09/2024
---------------------	-------------------------	-----------------------	-----------

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

Indication Requirements

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 mental illnesses, disorders or conditions.
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 serious immunological diseases.
Label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.



Australian Government
Department of Health, Disability and Ageing
Therapeutic Goods Administration

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

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

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

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

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

Other Ingredients (Excipients)

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

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.