Department of Health, Disability and Ageing

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 330611 Liquid Multivitamin with iron

ARTG entry for Medicine Listed

Sponsor Brauer Nutrition Pty Ltd

Postal Address PO Box 234, Tanunda, SA, 5352

2/03/2020 ARTG Start Date **Product Category** Medicine Status Active

Listed Medicines Approval Area

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 with iron

Product Type Effective Date 21/08/2024 Single Medicine Product

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 eve 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

Aids/assists teeth development in children

Maintain/support healthy teeth in children

Maintain/support healthy teeth in teenagers

Maintain/support teeth mineralisation in children

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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 children

Maintain/support red blood cell health in teenagers

Maintain/support blood health in teenagers

Maintain/support blood health in children

Helps maintain/support transport of oxygen in the body in children

Helps maintain/support transport of oxygen in the body in teenagers

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 teenagers

Maintain/support healthy immune system function in children

Maintain/support muscle function in teenagers

Maintain/support muscle function in children

Maintain/support healthy neuromuscular system/function in teenagers

Maintain/support healthy neuromuscular system/function in children

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 children

Aid/assist/helps protein synthesis in the body in teenagers

 ${\it Maintain/support\ absorption\ of\ dietary\ (state\ vitamin/mineral/nutrient)\ in\ children}$

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 when sun exposure is inadequate in children

Maintain/support (state vitamin/mineral/nutrient) levels in the body when sun exposure is inadequate in teenagers

Maintain/support (state vitamin/mineral/nutrient) levels in the body in children

Helps prevent dietary (state vitamin/mineral/nutrient) deficiency in children

 $\label{thm:lemma$

 ${\bf Aid/assist/helps\ metabolism\ of\ (state\ vitamin/mineral/nutrient)\ in\ children}$

Aid/assist/helps metabolism of (state vitamin/mineral/nutrient) in teenagers

Maintain/support cognitive development in children

Maintain/support cognitive function/mental function in children

Maintain/support cognitive function/mental function in teenagers

Maintain/support nerve conduction in children

Maintain/support nerve conduction in teenagers

Aid/assist/helps synthesis of neurotransmitters in children

Aid/assist/helps synthesis of neurotransmitters in teenagers

Maintain/support nervous system health in children

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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 teenagers

Maintain/support skin health in children

Maintain/support skin integrity/structure in teenagers

Maintain/support skin integrity/structure in children

Maintain/support skin regeneration in teenagers

Maintain/support skin regeneration in children

Maintain/support wound healing in teenagers

Maintain/support wound healing in children

Indication Requirements

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

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

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

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

If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake of dietary calories and increased

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 the table in Part 2 of Schedule 1 to this instrument are also used

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).

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

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 chronic fatigue syndrome

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 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

Additional Product information

Pack Size/Poison information

Pack Size Poison Schedule

Components

1 . Formulation 1

Oral Liquid Dosage Form Route of Administration Oral

Visual Identification

Active Ingredients

betacarotene 1 mg/mL Biotin 1.6 microgram/mL 3.41 mg/mL calcium ascorbate dihydrate

Equivalent: ascorbic acid 2.8 mg/mL

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calcium phosphate

Equivalent: calcium

choline bitartrate

Equivalent: choline

colecalciferol

d-alpha-tocopheryl acetate

dibasic magnesium phosphate trihydrate

Equivalent: magnesium ferric pyrophosphate

Equivalent: iron

levomefolate glucosamine

Equivalent: levomefolic acid

manganese amino acid chelate

Equivalent: manganese

mecobalamin nicotinamide potassium iodide Equivalent: iodine

pyridoxal 5-phosphate monohydrate

Equivalent: pyridoxine
riboflavin sodium phosphate
Equivalent: riboflavin

thiamine hydrochloride Equivalent: thiamine

zinc glycinate

Equivalent: zinc

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

26.4325 mg/mL

10.0007 mg/mL

20 mg/mL

8.26 mg/mL

.5 microgram/mL

2 mg/mL 24 mg/mL 3.3 mg/mL

3.325 mg/mL 1 mg/mL

· ...g/..._

72.13 microgram/mL

40 microgram/mL

1 mg/mL

200 microgram/mL .18 microgram/mL 400 microgram/mL 11.8 microgram/mL 9 microgram/mL

176 microgram/mL 100 microgram/mL 80 microgram/mL 60 microgram/mL 89 microgram/mL 80 microgram/mL

4 mg/mL 1.2 mg/mL

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