



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	398523	BN Chews Iron Free
ARTG entry for	Medicine Listed	
Sponsor	Pracmed Healthcare	
Postal Address	Unit 21 / 43 Lang Parade, Milton, QLD, 4064 Australia	
ARTG Start Date	27/10/2022	
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 . BN Chews Iron Free

Product Type	Single Medicine Product	Effective Date	27/10/2022
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Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Maintain/support energy levels
- Maintain/support body metabolism/metabolic rate
- Maintain/support energy production
- Helps maintain/support healthy eye development
- Maintain/support healthy eye function
- Maintain/support eye health
- Maintain/support healthy eyesight/vision
- Maintain/support body electrolyte balance
- Maintain/support healthy growth and development
- Maintain/support general health and wellbeing
- Maintain/support hair health
- Maintain/support nail health/strength/thickness
- Aid/assist in the healing of minor body tissue injuries
- Maintain/support bone health
- Aids/assists healthy bone development/growth/building
- Maintain/support (state mineral) absorption in bones
- Aid/assist healthy red blood cell production
- Maintain/support red blood cell health
- Helps maintain/support healthy blood sugar/glucose
- Helps maintain/support transport of oxygen in the body
- Helps maintain/support haemoglobin formation/synthesis
- Maintain/support cardiovascular system health
- Helps maintain/support healthy heart function
- Maintain/support healthy cardiovascular system function
- Maintain/support blood capillary health
- Maintain/support blood vessel health

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- Maintain/support healthy thyroid gland function
- Aid/assist thyroid hormone production
- Maintain/support immune system health
- Maintain/support healthy immune system function
- Maintain/support muscle function
- Aid/assist/helps glucose/sugar/carbohydrate metabolism
- Aid/assist/helps protein synthesis in the body
- Enhance/improve/promote/increase (state vitamin/mineral/nutrient) levels in the body
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
- Decrease/reduce/relieve symptoms of stress
- Aid/assist/helps synthesis of neurotransmitters
- Maintain/support nervous system health
- Maintain/support nervous system function
- Maintain/support reproductive system health
- Maintain/support healthy reproductive hormones
- Maintain/support skin health
- Maintain/support wound healing

Indication Requirements

- 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 cardiovascular conditions.
- Product presentation must not imply or refer to any thyroid related diseases.
- 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 mental illnesses, disorders or conditions.
- 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 heart disease.
- Product presentation must not imply or refer to chronic fatigue syndrome.
- Product presentation must not imply or refer to infertility.
- Product presentation must not imply or refer to hormone imbalances.
- Product presentation must not imply or refer to circulatory disorders/diseases/conditions e.g. thrombosis.
- Product presentation must not imply or refer to serious immunological diseases.
- Product presentation must not imply or refer to lowering or raising blood sugar/glucose levels from outside of the normal healthy range.
- 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).
- 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).

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

- This medicine contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.
- Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.
- The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.
- (If medicine contains one sugar) contains [insert name of sugar] OR (If medicine contains two or more sugars) Contains sugars [or words to that effect].

Additional Product information

Pack Size/Poison information

Pack Size

Poison Schedule

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Components

1 . Formulation 1

Dosage Form Tablet, chewable

Route of Administration Oral

Visual Identification

Active Ingredients

ascorbic acid	60 mg
betacarotene	2.1 mg
Biotin	150 microgram
calcium citrate tetrahydrate	71.09 mg
Equivalent: calcium	15 mg
calcium hydrogen phosphate dihydrate	580.9 mg
Equivalent: calcium	135 mg
calcium pantothenate	5 mg
Equivalent: calcium	420 microgram
Equivalent: pantothenic acid	4.58 mg
choline bitartrate	2.5 mg
Equivalent: choline	1.03 mg
chromic chloride hexahydrate	179.4 microgram
Equivalent: chromium	35 microgram
chromium picolinate	201.1 microgram
Equivalent: chromium	25 microgram
colecalfiferol	.0125 mg
cupric citrate hemipentahydrate	1.06 mg
Equivalent: copper	375 microgram
cyanocobalamin	125 microgram
d-alpha-tocopheryl acid succinate	12.4 mg
Equivalent: d-alpha-tocopheryl acid succinate	15 IU
folic acid	250 microgram
heavy magnesium oxide	90.69 mg
Equivalent: magnesium	52.5 mg
inositol	10 mg
manganese amino acid chelate	10 mg
Equivalent: manganese	1 mg
mecobalamin	125 microgram
molybdenum trioxide	56.3 microgram
Equivalent: molybdenum	37.5 microgram
nicotinamide	25 mg
potassium iodide	98.1 microgram
Equivalent: iodine	75 microgram
Equivalent: potassium	23.1 microgram
pyridoxine hydrochloride	.79 mg
Equivalent: pyridoxine	.65 mg
riboflavin	5 mg
selenomethionine	37.3 microgram
Equivalent: selenium	15 microgram
thiamine nitrate	5 mg
Equivalent: thiamine	4.05 mg
zinc amino acid chelate	37.5 mg
Equivalent: zinc	7.5 mg

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Other Ingredients (Excipients)

Acacia
carmellose sodium
citric acid
colloidal anhydrous silica
dl-alpha-tocopherol
Flavour
glucose monohydrate
hypromellose
iron oxide red
iron oxide yellow
magnesium stearate
maize starch
maltodextrin
medium chain triglycerides
Pea Starch
povidone
purified water
silicon dioxide
sodium alginate
sucralose
sucrose
thaumatin
xylitol

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