



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	304293	Hangover Relief
ARTG entry for	Medicine Listed	
Sponsor	Body Armour Pty Ltd	
Postal Address	5 Glenbrook Street, Everton Park, QLD, 4053 Australia	
ARTG Start Date	14/06/2018	
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.

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 . Hangover Relief

Product Type	Single Medicine Product	Effective Date	26/06/2020
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Permitted Indications

- Maintain/support collagen formation
- Maintain/support energy levels
- Helps convert (state food) into energy
- Maintain/support heat/energy production/thermogenesis
- Maintain/support healthy eye function
- Maintain/support eye health
- Maintain/support body mucous membrane health
- Maintain/support general health and wellbeing
- Maintain/support hair growth
- Maintain/support hair health
- Maintain/support healthy teeth
- Aid/assist nail growth
- Maintain/support nail health/strength/thickness
- Maintain/support connective tissue health
- Aid/assist/helps connective tissue production/formation
- Maintain/support healthy body tissues
- Maintain/support bone health
- Aid/assist healthy red blood cell production
- Maintain/support red blood cell health
- Maintain/support blood health
- Helps maintain/support haemoglobin formation/synthesis
- Maintain/support heart health
- Maintain/support blood capillary health

Public Summary



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Maintain/support blood vessel health
Traditionally used in Western herbal medicine to help reduce occurrence of symptoms of indigestion/dyspepsia
Traditionally used in Chinese medicine to decrease/reduce/relieve abdominal feeling of fullness
Traditionally used in Western herbal medicine to maintain/support gallbladder function
Traditionally used in Western herbal medicine to promote bile flow from liver/choloretic
Traditionally used in Western herbal medicine to help maintain/support bile secretion/flow
Traditionally used in Chinese medicine to help decrease/reduce/relieve symptoms of occasional hangovers
Maintain/support immune system health
Maintain/support healthy immune system function
Maintain/support muscle function
Aid/assist/helps protein synthesis in the body
Maintain/support absorption of dietary (state vitamin/mineral/nutrient)
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)
Aids/assists the body to cope with environmental stress
Support healthy stress response in the body
Traditionally used in Chinese medicine to relieve irritability
Traditionally used in Chinese medicine to decrease/reduce/relieve headache symptoms
Maintain/support nerve conduction
Aid/assist/helps synthesis of neurotransmitters
Maintain/support nervous system health
Maintain/support nervous system function
Maintain/support skin health
Maintain/support wound healing

Indication Requirements

Product presentation must not imply or refer to serious immunological diseases.
Label statement: If symptoms persist, talk to your health professional.
Product presentation must not imply or refer to serious cardiovascular conditions.
Product presentation must not imply or refer to liver disease, such as cirrhosis, hepatitis.
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.
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.
Label statement: Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.
Product presentation must not imply or refer to disease in any body organ.
Product presentation must not encourage excessive or harmful consumption of alcohol or other toxic substances.
Product presentation must not imply or refer to gastro oesophageal reflux disease.
Product presentation must not imply or refer to circulatory disorders/diseases/conditions e.g. thrombosis.
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 and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.
If symptoms persist, seek the advice of a healthcare professional.
(If the medicine contains one sorbate) Contains [insert name of sorbate] OR (if medicine contains two or more sorbates) Contains sorbates [or words to that effect].
Contains potassium. If you have kidney disease or are taking heart or blood pressure medicines, consult your doctor or pharmacist before use. Keep out of reach of children.
(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].
If symptoms persist consult your healthcare practitioner (or words to that effect).



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(If medicine contains one benzoate) Contains [insert name of benzoate] Or (If medicine contains two or more benzoates) Contains benzoates [or words to that effect].

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

ascorbic acid	9.9 mg/mL
calcium pantothenate	.0656 mg/mL
Equivalent: pantothenic acid	.06 mg/mL
cyanocobalamin	.005 mg/mL
cysteine hydrochloride monohydrate	5 mg/mL
Equivalent: cysteine	3.45 mg/mL
fructose	18 mg/mL
glucose monohydrate	18 mg/mL
Hovenia dulcis	3 mg/mL
Equivalent: Hovenia dulcis	30 mg/mL
magnesium citrate	1.85 mg/mL
Equivalent: magnesium	.3 mg/mL
monobasic potassium phosphate	.843 mg/mL
Equivalent: potassium	.2422 mg/mL
nicotinamide	.16 mg/mL
potassium chloride	3.75 mg/mL
Equivalent: potassium	1.97 mg/mL
Pueraria lobata	3 mg/mL
Equivalent: Pueraria lobata	30 mg/mL
pyridoxine hydrochloride	.0243 mg/mL
Equivalent: pyridoxine	.02 mg/mL
riboflavin sodium phosphate	.0263 mg/mL
Equivalent: riboflavin	.02 mg/mL
Silybum marianum	1.71 mg/mL
Equivalent: Silybum marianum	119.7 mg/mL
thiamine nitrate	.0247 mg/mL
Equivalent: thiamine	.02 mg/mL

Other Ingredients (Excipients)

carmellose sodium
 citric acid
 Flavour
 potassium sorbate
 purified water
 sodium benzoate
 sodium chloride
 sucralose

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