



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	314753	HCL Capsules
ARTG entry for	Medicine Listed	
Sponsor	Bio Concepts Pty Ltd	
Postal Address	PO Box 190, Banyo, Brisbane, QLD, 4014 Australia	
ARTG Start Date	25/02/2019	
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.

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.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

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 . HCL Capsules

Product Type	Single Medicine Product	Effective Date	25/02/2019
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Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Helps reduce/decrease free radical damage to body cells
- Traditionally used in Western herbal medicine to relieve feelings of general malaise/general debility
- Maintain/support healthy eye function
- Maintain/support eye health
- Maintain/support healthy eyesight/vision
- Maintain/support healthy growth and development
- Traditionally used in Western herbal medicine to restorative tonic
- Maintain/support general health and wellbeing
- Traditionally used in Western herbal medicine to decrease/reduce/relieve mild joint aches and pains
- Traditionally used in Western herbal medicine to decrease/reduce/relieve mild joint pain/soreness
- Traditionally used in Western herbal medicine to maintain/support blood circulation/flow to the peripheral areas of the body (legs, hands and feet)
- Traditionally used in Western herbal medicine to decrease/reduce/relieve loss of appetite
- Traditionally used in Western herbal medicine to maintain/support healthy appetite
- Traditionally used in Western herbal medicine to decrease/reduce/relieve colic (wind/gas pain)
- Traditionally used in Western herbal medicine to decrease/reduce/relieve flatulence/carminative
- Traditionally used in Western herbal medicine to maintain/support healthy digestive system function
- Traditionally used in Western herbal medicine to bitter tonic/stimulate gastric secretions
- Traditionally used in Western herbal medicine to maintain/support digestive system health

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Traditionally used in Western herbal medicine to help reduce occurrence of symptoms of indigestion/dyspepsia
Traditionally used in Western herbal medicine to decrease/reduce/relieve abdominal bloating/distention
Traditionally used in Western herbal medicine to relieve digestive discomfort
Traditionally used in Western herbal medicine to improve digestive weakness
Traditionally used in Western herbal medicine to decrease/reduce/relieve nausea
Maintain/support immune system health
Maintain/support healthy immune system function
Traditionally used in Western herbal medicine to decrease/reduce/relieve muscle pain/ache/soreness
Aid/assist/helps protein synthesis in the body
Maintain/support (state vitamin/mineral/nutrient) levels in the body
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)
Maintain/support nervous system health
Maintain/support nervous system function
Maintain/support female reproductive system health
Maintain/support/regulate healthy menstrual cycle
Maintain/support reproductive system health
Maintain/support healthy reproductive hormones
Maintain/support skin health
Maintain/support skin integrity/structure
Maintain/support wound healing in healthy individuals
Maintain/support skin repair/healing/regeneration

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 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 only refer to mild joint symptoms.
Product presentation must not imply or refer to gastro oesophageal reflux disease.
Product presentation must not imply or refer to hormone imbalances.
Product presentation must not imply or refer to infertility.
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 eating disorders.
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 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.

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 consult your healthcare practitioner (or words to that effect).

Additional Product information

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

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Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

Gentiana lutea root Extract dry concentrate	40 mg
Equivalent: Gentiana lutea (Dry)	160 mg
zinc citrate dihydrate	15.6 mg
Equivalent: zinc	5 mg
Zingiber officinale root Extract dry concentrate	40 mg
Equivalent: Zingiber officinale (Dry)	400 mg

Other Ingredients (Excipients)

betaine hydrochloride
colloidal anhydrous silica
disodium edetate
gellan gum
glycine
hypromellose
leucine
maltodextrin
potable water
potassium acetate

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