



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	314434	Glucolin
ARTG entry for	Medicine Listed	
Sponsor	Bio Concepts Pty Ltd	
Postal Address	PO Box 190, Banyo, Brisbane, QLD, 4014 Australia	
ARTG Start Date	19/02/2019	
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.

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 . Glucolin

Product Type	Single Medicine Product	Effective Date	22/09/2020
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Permitted Indications

Antioxidant/Reduce free radicals formed in the body
Helps reduce/decrease free radical damage to body cells
Maintain/support collagen formation
Maintain/support collagen health
Maintain/support natural liver cleansing/detoxification processes in healthy individuals
Maintain/support energy production
Maintain/support general health and wellbeing
Maintain/support connective tissue health
Aid/assist/helps connective tissue production/formation
Maintain/support bone health
Aids/assists healthy bone development/growth/building
Helps maintain/supports healthy joint cartilage growth/development/production
Helps maintain/support healthy blood sugar/glucose
Maintain/support cardiovascular system health
Aid/assist/helps glucose/sugar/carbohydrate metabolism
Aid/assist/helps protein synthesis in the body
Maintain/support (state vitamin/mineral/nutrient) levels in the body
Helps maintain/support cellular uptake of (state vitamin/mineral/nutrient)
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)

Indication Requirements

Product presentation must not imply or refer to drugs/alcohol.



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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 disease in any body organ, in particular the kidney or liver.

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 serious cardiovascular 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 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 detoxification in relation to natural body processes.

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.

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.

Additional Product information

Pack Size/Poison information

Pack Size **Poison Schedule**

Components

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

Biotin	2.2 mg
chromium picolinate	400 microgram
Equivalent: chromium	50 microgram
Cinnamomum cassia stem bark Extract dry concentrate	100 mg
Equivalent: Cinnamomum cassia (Dry)	1.5 g
leucine	200 mg
manganese amino acid chelate	20 mg
Equivalent: manganese	2 mg
Momordica charantia fruit Extract dry concentrate	100 mg
Equivalent: Momordica charantia (Dry)	800 mg

Other Ingredients (Excipients)

- colloidal anhydrous silica
- disodium edetate
- gellan gum
- glycine
- hypromellose
- potable water
- potassium acetate

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