



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	387803	Gluco Chrome
ARTG entry for	Medicine Listed	
Sponsor	Interclinical Laboratories Pty Ltd	
Postal Address	PO Box 6474, ALEXANDRIA, NSW, 2015 Australia	
ARTG Start Date	3/05/2022	
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 . Gluco Chrome

Product Type	Single Medicine Product	Effective Date	2/06/2022
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Permitted Indications

Maintain/support energy levels
Maintain/support energy production
Maintain/support body mucous membrane health
Maintain/support general health and wellbeing
Traditionally used in Western herbal medicine to astringent/tightens tissues
Helps maintain/support healthy blood sugar/glucose in healthy individuals
Traditionally used in Western herbal medicine to decrease/reduce/relieve flatulence/carminative
Traditionally used in Western herbal medicine to relieve digestive discomfort
Traditionally used in Western herbal medicine to decrease/reduce/relieve digestive spasms
Aid/assist/helps glucose/sugar/carbohydrate metabolism
Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)
Maintain/support nervous system health
Maintain/support nervous system function
Maintain/support skin health

Indication Requirements

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

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

Product presentation must not imply or refer to gastro oesophageal reflux disease.

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 lowering or raising blood sugar/glucose levels from outside of the normal healthy range.

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 chronic fatigue syndrome.

Standard Indications

No Standard Indications included on Record



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Specific Indications

No Specific Indications included on Record

Warnings

Do not take while on warfarin therapy without medical advice.

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

alpha lipoic acid	33.5 mg
chromic chloride hexahydrate	821 microgram
Equivalent: chromium	160 microgram
chromium picolinate	121 microgram
Equivalent: chromium	15 microgram
Cinnamomum verum stem bark Extract dry concentrate	75 mg
Equivalent: Cinnamomum verum (Dry)	750 mg
cysteine hydrochloride monohydrate	10.509 mg
Equivalent: cysteine	7.25 mg
glutamine	10 mg
glycine	10 mg
Momordica charantia fruit Extract dry concentrate	100 mg
Equivalent: Momordica charantia (Fresh)	32 g
nicotinamide	10 mg
ubidecarenone	25 mg

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
colloidal anhydrous silica
croscarmellose sodium
hypromellose
magnesium stearate

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