

Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 169111 GlucoPlex

ARTG entry for Medicine Listed

Sponsor Herbs of Gold Pty Ltd

Postal Address PO Box 3143, KIRRAWEE, NSW, 2232

Australia

ARTG Start Date 15/02/2010

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 . GlucoPlex

Product Type Single Medicine Product Effective Date 2/02/2021

Permitted Indications

Antioxidant/Reduce free radicals formed in the body

Helps maintain/support healthy blood sugar/glucose

Aid/assist/helps glucose/sugar/carbohydrate metabolism

Indication Requirements

Product presentation must not imply or refer to lowering or raising blood sugar/glucose levels from outside of the normal healthy range.

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.

WARNING: May be dangerous if taken in large amounts or for a long period. OR WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).

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

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alpha lipoic acid 200 mg 256.3 microgram chromic chloride hexahydrate Equivalent: chromium 50 microgram chromium picolinate 133.5 microgram Equivalent: chromium 16.6 microgram Cinnamomum cassia stem bark Extract dry concentrate 66.67 mg Equivalent: Cinnamomum cassia (Dry) 1 g colecalciferol .0083 mg Gymnema sylvestre leaf Extract dry concentrate standardised 100 mg Equivalent: Gymnema sylvestre (Dry) 2 g nicotinamide 35 mg Trigonella foenum-graecum seed Extract dry concentrate 4 mg Equivalent: Trigonella foenum-graecum (Dry) 500 mg zinc amino acid chelate 50 mg Equivalent: zinc 10 mg

Other Ingredients (Excipients)

Acacia

carrageenan

colloidal anhydrous silica

crospovidone

dl-alpha-tocopherol

hypromellose

magnesium stearate

maize starch

medium chain triglycerides microcrystalline cellulose

potassium acetate

povidone

purified water

silicon dioxide

sucrose

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