

Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 273167 Chromium Excel

ARTG entry for Medicine Listed

 Sponsor
 McPherson's Consumer Products Pty Ltd

 Postal Address
 Locked Bag 5018, Kingsgrove, NSW, 2208

Australia

ARTG Start Date 21/03/2016

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 . Chromium Excel

Product Type Single Medicine Product Effective Date 8/10/2020

Permitted Indications

Helps maintain/support healthy blood sugar/glucose

Aid/assist digestion/breakdown of dietary fat

Aid/assist/helps glucose/sugar/carbohydrate metabolism

Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)

Indication Requirements

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

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.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

No Warnings included on Record

Additional Product information

Pack Size/Poison information

Pack Size Poison Schedule

Components

1 . Formulation 1

Dosage Form Tablet, film coated

Route of Administration Oral

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Visual Identification

Anthur Inner dianta	
Active Ingredients	
chromic chloride hexahydrate	1.025 mg
Equivalent: chromium	200 microgram
Garcinia gummi-gutta fruit peel Extract dry concentrate standardised	500 mg
Equivalent: Garcinia gummi-gutta (Dry)	2.5 g
Gymnema sylvestre leaf Extract dry concentrate standardised	77 mg
Equivalent: Gymnema sylvestre (Dry)	1.54 g
hydroxycitrate complex	250 mg
Equivalent: hydroxycitric acid	150 mg
Piper nigrum fruit Extract dry concentrate standardised	5.37 mg
Equivalent: Piper nigrum (Dry)	110 mg
Plectranthus barbatus root Extract dry concentrate standardised	79.6 mg
Equivalent: Plectranthus barbatus (Dry)	4.975 g
Other Ingredients (Excipients)	

calcium hydrogen phosphate dihydrate

calcium hydroxide

Carnauba Wax

colloidal anhydrous silica

croscarmellose sodium

hypromellose

macrogol 400

magnesium stearate

maltodextrin

microcrystalline cellulose

povidone

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