Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 310445 Cranberry 70 000

ARTG entry for Medicine Listed

Sponsor Herbs of Gold Pty Ltd

Postal Address PO Box 3143, KIRRAWEE, NSW, 2232

Australia

ARTG Start Date 17/10/2018
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 . Cranberry 70 000

Product Type Single Medicine Product Effective Date 14/07/2023

Permitted Indications

Antioxidant/Reduce free radicals formed in the body

Maintain/support general health and wellbeing

Maintain/support immune system health

Maintain/support healthy immune system function

Helps reduce occurrence of medically diagnosed cystitis

Traditionally used in Western herbal medicine to helps reduce occurrence of medically diagnosed cystitis

Traditionally used in Western herbal medicine to maintain/support urinary tract health

Maintain/support urinary tract health

Indication Requirements

Product presentation must not imply or refer to serious immunological diseases.

Label statement: If pain or irritation persists for more than 48 hours, consult your doctor. The presence of blood in the urine warrants immediate medical attention (or words to that effect).

Product presentation must only refer to medically diagnosed cystitis.

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

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1 . Formulation 1

Dosage Form Tablet, film coated

Route of Administration Oral

Visual Identification

Active Ingredients

ascorbic acid100 mgVaccinium macrocarpon fruit Extract dry concentrate140 mgEquivalent: Vaccinium macrocarpon (Fresh)70 g

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate

colloidal anhydrous silica

crospovidone

hypromellose

macrogol 400

magnesium stearate

microcrystalline cellulose

sodium starch glycollate

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