Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 365790 Soforwe Gut Relief Plus

ARTG entry for Medicine Listed

Sponsor Nutrition Care Pharmaceuticals Pty Ltd

Postal Address 25-31 Keysborough Avenue, Keysborough, VIC, 3173

Australia

ARTG Start Date 13/05/2021

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 . Soforwe Gut Relief Plus

Product Type Single Medicine Product Effective Date 31/05/2023

Permitted Indications

Antioxidant/Reduce free radicals formed in the body

Helps reduce/decrease free radical damage to body cells

Maintain/support energy production

Maintain/support eye health

Helps maintain/support healthy acid/alkali balance in the body

Maintain/support general health and wellbeing

Maintain/support joint health

Maintain/support joint mobility/flexibility

Maintain/support blood capillary health

Maintain/support healthy mucous linings of the digestive system

Maintain/support gastrointestinal system health

Maintain/support healthy gastrointestinal function

Maintain/support gastrointestinal mucosal membrane health

Maintain/support immune system health

Maintain/support healthy immune system function

Maintain/support healthy gastrointestinal immune function

Maintain/support muscle health

Aid/assist/helps protein synthesis in the body

Support healthy body stress recovery

Indication Requirements

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 vision correction, faults or serious eye disease e.g. macular degeneration.

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

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.

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

Product presentation must not imply or refer to circulatory disorders/diseases/conditions e.g. thrombosis.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

If symptoms persist, seek the advice of a healthcare professional.

Contains crustacea OR Contains crustacean products.

Additional Product information

Pack Size/Poison information

Pack Size Poison Schedule

Components

1 . Formulation 1

Dosage FormPowderRoute of AdministrationOral

Visual Identification

Active Ingredients

curcumin 1.2755 mg/g 52 mg/g dibasic sodium phosphate glucosamine hydrochloride 100 mg/g glutamine 500 mg/g **Guar Gum** 20 mg/g Lactobacillus reuteri 2 mg/g pectin 20 mg/g Peppermint Oil 600 microgram/g 40 mg/g

Ulmus rubra stem bark inner Powder 40 mg/g

Other Ingredients (Excipients)

Aloe vera

betadex

colloidal anhydrous silica

dextrin

maltodextrin

Stevia rebaudiana

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