Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 321710 ETHICAL NUTRIENTS MEGA MAGNESIUM MUSCLE PLUS

ARTG entry for Medicine Listed

Sponsor Metagenics (Aust) Pty Ltd

Postal Address PO Box 675, VIRGINIA BC, QLD, 4014

Australia

ARTG Start Date 13/08/2019
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. ETHICAL NUTRIENTS MEGA MAGNESIUM MUSCLE PLUS

Product Type Single Medicine Product Effective Date 7/07/2021

Permitted Indications

Decrease/reduce/relieve muscle cramps

Maintain/support muscle function

Helps enhance/promote healthy muscle mass during resistance training

Maintain/support muscle mass in elderly individuals

Maintain/support healthy neuromuscular system/function when dietary intake is inadequate

Maintain/support healthy neuromuscular system/function

Maintain/support muscle strength

Indication Requirements

Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.

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

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet. If symptoms persist consult your healthcare practitioner (or words to that effect).

Additional Product information

Pack Size/Poison information

Pack Size Poison Schedule

Components

1 . Formulation 1

Page 1 of 2



Australian Government

Department of Health

Therapeutic Goods Administration

307.38 mg/g

Dosage FormPowderRoute of AdministrationOral

Visual Identification

Active Ingredients

calcium beta-hydroxy-beta-methylbutyrate monohydrate

colecalciferol 2.0491 microgram/g

magnesium glycinate dihydrate344.26 mg/gEquivalent: magnesium34.43 mg/g

Other Ingredients (Excipients)

Acacia

ascorbic acid ascorbyl palmitate

carotenes

citric acid

dl-alpha-tocopherol

Flavour

maize starch

malic acid

maltodextrin

medium chain triglycerides

Olive Oil

purified water

silicon dioxide

Steviol glycosides

sucrose

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