Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 164609 Vitamin B2 200mg

ARTG entry for Medicine Listed

Sponsor Herbs of Gold Pty Ltd

Postal Address PO Box 3143, KIRRAWEE, NSW, 2232

Australia

ARTG Start Date 25/08/2009

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 . Vitamin B2 200mg

Product Type Single Medicine Product Effective Date 20/12/2022

Permitted Indications

Antioxidant/Reduce free radicals formed in the body

Maintain/support energy production

Maintain/support eye health

Maintain/support general health and wellbeing

Maintain/support hair health

Maintain/support body tissue repair/regeneration

Maintain/support cardiovascular system health

Maintain/support (state vitamin/mineral/nutrient) levels in the body

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

Helps reduce occurrence of mild migraines

Decrease/reduce duration of mild migraine

Maintain/support skin health

Indication Requirements

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

Product presentation must only refer to mild migraine.

Product presentation must not imply or refer to vision correction, faults or serious eye disease e.g. macular degeneration.

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).

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 serious cardiovascular conditions.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

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Warnings

Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin 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

Dosage Form Tablet, film coated

Route of Administration

Visual Identification

Active Ingredients

riboflavin 200 mg

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate

colloidal anhydrous silica

hypromellose

macrogol 400

magnesium stearate

microcrystalline cellulose

sodium starch glycollate

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