Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 220238 BLACKMORES MAGMIN

ARTG entry for Medicine Listed

Sponsor Blackmores Ltd

Postal Address PO Box 1725, WARRIEWOOD, NSW, 2102

Australia

ARTG Start Date 18/02/2014

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. BLACKMORES MAGMIN

Product Type Single Medicine Product Effective Date 5/04/2023

Permitted Indications

Maintain/support body metabolism/metabolic rate

Maintain/support body electrolyte balance

Maintain/support general health and wellbeing

Aids/assists teeth development

Maintain/support healthy teeth

Maintain/support bone health

Maintain/support muscle function

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

Helps prevent dietary (state vitamin/mineral/nutrient) deficiency

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

Indication Requirements

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).

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 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

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

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Pack Size/Poison information

Pack Size Poison Schedule

Components

1 . Formulation 1

Dosage Form Tablet, film coated

Route of Administration Oral

Visual Identification

Active Ingredients

magnesium aspartate dihydrate500 mgEquivalent: magnesium37.4 mg

Other Ingredients (Excipients)

Carnauba Wax

colloidal anhydrous silica

croscarmellose sodium

hypromellose

macrogol 8000

magnesium stearate

microcrystalline cellulose

purified talc

sodium starch glycollate

titanium dioxide

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