

Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 320575 Z-MAG

ARTG entry for Medicine Listed

Sponsor ATP Science Pty Ltd

Postal Address 5/63-69 Meakin Road, Meadowbrook, QLD, 4131

Australia

ARTG Start Date 23/07/2019
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.Z-MAG

Product Type Single Medicine Product Effective Date 4/03/2024

Permitted Indications

Maintain/support energy levels

Maintain/support hair health

Maintain/support nail health/strength/thickness

Maintain/support bone health

Maintain/support healthy immune system function

Decrease/reduce/relieve muscle cramps

Helps decrease/reduce/relieve mild muscle spasms/twitches

Maintain/support muscle health

Maintain/support muscle function

Maintain/support muscle relaxation

Decrease/reduce/relieve muscle pain/ache/soreness

Aid/assist/helps mind relaxation

Decrease/reduce/relieve nervous tension/unrest

Maintain/support general mental wellbeing

Maintain/support nervous system health

Maintain/support nervous system function

Maintains/supports refreshing sleep

Maintain/support healthy sleeping patterns

Indication Requirements

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

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

Product presentation must not imply or refer to chronic fatigue syndrome.

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.

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

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

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

This medicine contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.

Additional Product information

Pack Size/Poison information

Pack Size Poison Schedule

Components

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

 high selenium yeast
 3.13 mg

 Equivalent: selenium
 6.25 microgram

 magnesium citrate
 647.25 mg

 Equivalent: magnesium
 100 mg

 taurine
 25 mg

 zinc gluconate
 19.23 mg

 Equivalent: zinc
 2.5 mg

Other Ingredients (Excipients)

Acacia

colloidal anhydrous silica

hypromellose

magnesium stearate

microcrystalline cellulose

purified water

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