

# **Australian Government**

## **Department of Health**

# Therapeutic Goods Administration

## **Public Summary**

Summary for ARTG Entry: 262976 Eagle Nutra-Mag BioMuscle Powder

ARTG entry for Medicine Listed

Sponsor Integria Healthcare Australia Pty Ltd

Postal Address PO Box 4854, EIGHT MILE PLAINS, QLD, 4113

Australia

ARTG Start Date 12/11/2015
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.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

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 . Eagle Nutra-Mag BioMuscle Powder

Product Type Single Medicine Product Effective Date 21/04/2020

### **Permitted Indications**

Helps convert (state food) into energy

Maintain/support energy production

Maintain/support general health and wellbeing

Maintain/support healthy cardiovascular system function

Maintain/support healthy muscle contraction function

Maintain/support muscle health In older females

Maintain/support muscle health in females

Maintain/support muscle health

Maintain/support muscle function

Maintain/support healthy neuromuscular system/function

Maintain/support muscle relaxation

Maintain/support muscle relaxation in females

Maintain/support muscle relaxation In older females

Maintain/support muscle tone In older females

Maintain/support muscle tone in females

Maintain/support muscle tone

Aid/assist/helps glucose/sugar/carbohydrate metabolism

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

Maintain/support (state vitamin/mineral) within normal range

Maintain/support nerve conduction In older females

Maintain/support nerve conduction in females

Maintain/support nerve conduction

Aid/assist/helps synthesis of neurotransmitters

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## **Indication Requirements**

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

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

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.

Product presentation must not imply or refer to lowering or raising blood sugar/glucose levels from outside of the normal healthy range.

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

#### Standard Indications

No Standard Indications included on Record

### **Specific Indications**

No Specific Indications included on Record

### Warnings

For practitioner dispensing only.

WARNING - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. [Contains vitamin B6].

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

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.

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.

#### **Additional Product information**

## Pack Size/Poison information

Pack Size Poison Schedule

## Components

### 1. Formulation 1

Dosage Form Powder, oral **Route of Administration** Oral

Visual Identification

## **Active Ingredients**

ascorbic acid

20 mg/g calcium ascorbate dihydrate 16.231 mg/g Equivalent: ascorbic acid 13.334 mg/g calcium folinate 28 microgram/g Equivalent: folinic acid 20 microgram/g chromium picolinate 54 microgram/g Equivalent: chromium 6.7 microgram/g cyanocobalamin 6.67 microgram/g alutamine 66.67 mg/g magnesium amino acid chelate 13.333 mg/g Equivalent: magnesium 1.333 mg/g 100 mg/g magnesium amino acid chelate Equivalent: magnesium 10 mg/g magnesium aspartate dihydrate 7.12 mg/g Equivalent: magnesium 534 microgram/g magnesium citrate 186.25 mg/g Equivalent: magnesium 29.8 mg/g magnesium orotate dihydrate 15.152 mg/g

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Equivalent: magnesium 1 mg/g nicotinamide 2.67 mg/g potassium citrate 22.099 mg/g Equivalent: potassium 8 mg/g pyridoxal 5-phosphate 2.665 mg/g Equivalent: pyridoxine 1.824 mg/g pyridoxine hydrochloride 5.885 mg/g Equivalent: pyridoxine 4.842 mg/g selenomethionine 8.67 microgram/g Equivalent: selenium 3.47 microgram/g taurine 73.33 mg/g thiamine nitrate 4.11 mg/g Equivalent: thiamine 3.33 mg/g zinc amino acid chelate 4 mg/g

Equivalent: zinc 800 microgram/g

### Other Ingredients (Excipients)

ascorbic acid

beetroot

Beta vulgaris

Black currant

Blackberry

calcium hydrogen phosphate dihydrate

citric acid

colloidal anhydrous silica

Cranberry

Flavour

Hippophae rhamnoides

inulin

malic acid

Malpighia glabra

maltodextrin

Pomegranate

Raspberry

Salvia hispanica

Sambucus nigra

silicon dioxide

Stevia rebaudiana

Strawberry

tapioca starch

thaumatin

Vaccinium myrtillus

xanthan gum

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