



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	395190	MAG3 COMPLETE
ARTG entry for	Medicine Listed	
Sponsor	Ora Health Pty Ltd	
Postal Address	24/10-18 Orchard Road, Brookvale, NSW, 2100 Australia	
ARTG Start Date	31/08/2022	
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 . MAG3 COMPLETE

Product Type	Single Medicine Product	Effective Date	31/08/2022
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Permitted Indications

Maintain/support energy production
Maintain/support healthy growth and development
Maintain/support general health and wellbeing
Maintain/support healthy teeth
Maintain/support bone health
Aids/assists healthy bone development/growth/building
Help maintain/support bone mineralisation
Vitamin D helps calcium absorption (or words of like intent) and a diet deficient in calcium can lead to osteoporosis in later life
Aid/assist healthy red blood cell production
Maintain/support red blood cell health
Maintain/support blood health
Maintain/support cardiovascular system health
Maintain/support healthy cardiovascular system function
Maintain/support heart health
Maintain/support immune system health
Maintain/support healthy immune system function
Maintain/support muscle health
Maintain/support muscle function
Aid/assist/helps glucose/sugar/carbohydrate metabolism
Helps decrease/reduce homocysteine levels in healthy individuals
Aid/assist/helps protein synthesis in the body
Maintain/support absorption of dietary (state vitamin/mineral/nutrient)
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)
Maintain/support (state vitamin/mineral) within normal range
Maintain/support neuromuscular function



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Maintain/support nervous system health

Indication Requirements

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).

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Product presentation must not imply or refer to serious cardiovascular conditions.

Indication only for use for medicines that contain vitamin D as an active ingredient. The medicines may only contain a maximum recommended daily dose of 25 micrograms or less of vitamin D and as a minimum, also contain at least 25% of the RDI in the recommended daily dose of vitamin D.

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

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 immunological diseases.

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

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.

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.

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

colecalfiferol	.0125 mg
magnesium amino acid chelate	768.22 mg
Equivalent: magnesium	153.64 mg
magnesium citrate	100.35 mg
Equivalent: magnesium	15.5 mg
magnesium glycinate dihydrate	51.316 mg
Equivalent: magnesium	5.85 mg
mecobalamin (co-methylcobalamin)	25 microgram

Other Ingredients (Excipients)

Acacia

calcium hydrogen phosphate dihydrate

colloidal anhydrous silica

d-alpha-tocopherol

edetic acid

fractionated coconut oil

gellan gum

hypromellose

liquid glucose

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magnesium stearate
microcrystalline cellulose
potable water
potassium acetate
silicon dioxide
sodium ascorbate

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