

**Australian Government** 

## **Department of Health**

## Therapeutic Goods Administration

**Public Summary** 

Summary for ARTG Entry:	378593	Thompson's Organic Magnesium	
ARTG entry for	Medicine Listed		
Sponsor	Integria Healthcare Australia Pty Ltd		
Postal Address	PO Box 4854, E Australia	IGHT MILE PLAINS, QLD, 4113	
ARTG Start Date	23/11/2021		
Product Category	Medicine		
Status	Active		
Approval Area	Listed Medicines	3	
Conditions			

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 . Thompson's Organic Magnesium					
Product Type	Single Medicine Product	Effective Date	19/04/2022		
Permitted Indications	5				
Helps convert (state for	ood) into energy				
Maintain/support energy	gy production				
Maintain/support gene	ral health and wellbeing				
Maintain/support healt	hy cardiovascular system function				
Maintain/support healt	hy muscle contraction function				
Maintain/support muse	cle function				
Maintain/support healt	hy neuromuscular system/function				
Aid/assist/helps glucos	se/sugar/carbohydrate metabolism				
Maintain/support (state	e vitamin/mineral/nutrient) levels in the body				
Maintain/support (state	e vitamin/mineral) within normal range				
Aid/assist/helps synthe	esis of neurotransmitters				
Indication Requirement	ents				

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 musculoskeletal or neurological conditions.

Product presentation must not imply or refer to serious cardiovascular 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 physical activity.

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

### **Standard Indications**

No Standard Indications included on Record

# Specific Indications

No Specific Indications included on Record

### Warnings

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# Therapeutic Goods Administration

If symptoms persist consult your healthcare practitioner (or words to that effect).

Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.

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

### **Additional Product information**

ack Size	Poise	on Schedule	
omponents			
1. Formulation 1			
Dosage Form	Tablet, film coated		
Route of Administration	Oral		
Visual Identification			
Active Ingredients			
colecalciferol		.0025 mg	
Fucus vesiculosus whole	plant Extract dry concentrate	5 mg	
Equivalent: Fucus vesicul		25 mg	
magnesium amino acid cł	nelate	806 mg	
Equivalent: magnesium		161 mg	
magnesium aspartate dih	ydrate	100 mg	
Equivalent: magnesium		7.5 mg	
magnesium orotate dihyd	rate	100 mg	
Equivalent: magnesium		6.4 mg	
pyridoxine hydrochloride		30 mg	
Equivalent: pyridoxine		24.7 mg	
Other Ingredients (Excipie	ents)		
calcium hydrogen phosph	ate dihydrate		
colloidal anhydrous silica			
crospovidone			
dl-alpha-tocopherol			
hydrogenated soya oil			
hydrolysed gelatin			
hyprolose			
lecithin			
macrogol 3000			
magnesium stearate			
maize starch maltodextrin			
microcrystalline cellulose			
polyvinyl alcohol			
povidone			
purified talc			
silicon dioxide			

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