

**Australian Government** 

## **Department of Health**

# Therapeutic Goods Administration

**Public Summary** 

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Summary for ARTG Entry:	347720	Turmeric & Magnesium			
ARTG entry for	Medicine Listed	ł			
Sponsor	Phytologic Holdings Pty Limited				
Postal Address	16-20 Baker St Australia	reet, Banksmeadow, NSW, 201			
ARTG Start Date	9/11/2020				
Product Category	Medicine				
Status	Active				
Approval Area	Listed Medicine	es			
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. Turmeric &	Magnesium						
Product Type	Single Medicine Product	Effective Date	2/08/2022				
Permitted Indication	ons						
Antioxidant/Reduce	free radicals formed in the body						
Helps reduce/decre	ease free radical damage to body cells						
Maintain/support er	nergy levels when dietary intake is inadequa	te					
Maintain/support er	nergy production						
Maintain/support ge	eneral health and wellbeing						
Anti-inflammatory/relieve inflammation							
Maintain/support bo	one health						
Traditionally used in	n Ayurvedic medicine to decrease/reduce/re	lieve mild joint aches and pains					
Maintain/support ca	ardiovascular system health						
Relieve digestive di	iscomfort						
Decrease/reduce/relieve muscle cramps when dietary intake is inadequate							
Helps decrease/reduce/relieve mild muscle spasms/twitches when dietary intake is inadequate							
Maintain/support muscle health							
Maintain/support (state vitamin/mineral/nutrient) levels in the body							
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency when dietary intake is inadequate							
Aid/assist/helps me	tabolism of (state vitamin/mineral/nutrient)						
Maintain/support ne	ervous system health						
Maintain/support ne	ervous system function						

#### Indication Requirements

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

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).

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

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.

Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR

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[Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.

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

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

Product presentation must only refer to mild joint symptoms.

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

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

Contains magnesium, which may have a laxative effect or cause diarrhoea (or words to that effect). If symptoms persist consult your healthcare practitioner (or words to that effect).

# Additional Product information

Pack Size/Poison information	on			
Pack Size		Poison Schedule		
Components				
1. Formulation 1				
Dosage Form	Capsule, hard			
Route of Administration	Oral			
Visual Identification				
Active Ingredients				
Curcuma longa rhizome E	Extract dry concentrate		75 mg	
Equivalent: Curcuma long	ga (Dry)		1.5 g	
heavy magnesium oxide			165.81 mg	
Equivalent: magnesium			100 mg	
magnesium amino acid cl	helate		200 mg	
Equivalent: magnesium			40 mg	
magnesium citrate			453.07 mg	
Equivalent: magnesium			70 mg	
Piper nigrum fruit Extract	dry concentrate standardised		5.26 mg	
Equivalent: Piper nigrum	(Dry)		131.5 mg	
Other Ingredients (Excipi	ents)			
colloidal anhydrous silica	I			
hypromellose				
magnesium stearate				
maltodextrin				
purified water				
silicon dioxide				

sorbitol

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