

Australian Government

## **Department of Health and Aged Care**

Therapeutic Goods Administration

**Public Summary** 

Summary for ARTG Entry:	393773	My Pure Magnesium
ARTG entry for	Medicine Listed	
Sponsor	Thera Health Pt	y Ltd
Postal Address	18/93 Rivergate Australia	Place, Murarrie, QLD, 4172
ARTG Start Date	11/08/2022	
Product Category	Medicine	
Status	Active	
Approval Area	Listed Medicine	S
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.

roducts			
1 . My Pure M	agnesium		
Product Type	Single Medicine Product	Effective Date	11/08/2022
Permitted Indicat	ions		
Maintain/support h	ealthy cardiovascular system function		
Decrease/reduce/r	elieve muscle cramps		
Maintain/support (s	state vitamin/mineral/nutrient) levels in the bo	dy	
Maintain/support b	rain health		
Maintain/support n	ervous system health		
Indication Require	ements		
Label statement: I	f symptoms persist, talk to your health profes	sional.	
	ted for supplementation, Label statement: [V itamins/minerals/nutrients/dietary supplement		upplements] can only be of assistance if dietary intake is iet (or words to that effect).
Product presentat	ion must not imply or refer to serious cardiova	ascular conditions.	
Product presentat	ion must not imply or refer to mental illnesses	s, disorders or conditions.	
Product presentat	ion must not imply or refer to serious muscule	oskeletal or neurological conditions.	
Standard Indicati	ons		
No Standard Indica	ations included on Record		
Specific Indicatio	ns		
No Specific Indicat	ions included on Record		
Warnings			
No Warnings inclue	ded on Record		
Additional Produc	ct information		
Pack Size/Poison	information		
Pack Size		Poison Schedule	
Components			

1. Formulation 1

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Dosage FormCapsule, hardRoute of AdministrationOralVisual IdentificationTopActive Ingredients750 mgEquivalent: magnesium150 mgOther Ingredients (ExcipeSecurity (Security))Colloidal anhydrous silicaSecurity (Security)hypromelloseSecurity (Security)I eucineSecurity (Security)

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