



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	60890	COLON CLEANSE
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Denmar International Pty Ltd	
<b>Postal Address</b>	291 Warwick Road, GREENWOOD, WA, 6024 Australia	
<b>ARTG Start Date</b>	5/08/1997	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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 . COLON CLEANSE

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	28/01/2021
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### Permitted Indications

Maintain/support energy levels  
Maintain/support energy production  
Maintain/support body electrolyte balance  
Maintain/support general health and wellbeing  
Maintain/support healthy teeth  
Maintain/support bone health  
Maintain/support cardiovascular system health  
Maintain/support healthy cardiovascular system function  
Maintain/support heart health  
Decrease/reduce/relieve constipation  
Aperient/laxative  
Maintain/support healthy immune system function  
Maintain/support muscle function  
Maintain/support healthy neuromuscular system/function  
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency  
Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)  
Maintain/support nerve conduction  
Maintain/support nervous system health  
Maintain/support nervous system function

### Indication Requirements

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).

Label statement for stimulant laxatives: Prolonged use may cause serious bowel problems.

Product presentation must not refer to or imply weight loss.

Product presentation must not imply or refer to serious immunological diseases.

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Label statement: Do not use when abdominal pain, nausea or vomiting are present or if you develop diarrhoea. If you are pregnant or breastfeeding - seek the advice of a healthcare professional before taking this product (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.

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

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

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.

Label statement: Drink plenty of water (or words to that effect).

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

**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

No Specific Indications included on Record

**Warnings**

No Warnings included on Record

**Additional Product information**

**Pack Size/Poison information**

<b>Pack Size</b>	<b>Poison Schedule</b>
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**Components**

**1 . Formulation 1**

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

**Visual Identification**

**Active Ingredients**

<b>heavy magnesium oxide</b>	<b>800 mg/g</b>
Equivalent: magnesium	482.48 mg/g
<b>magnesium carbonate hydrate</b>	<b>200 mg/g</b>
Equivalent: magnesium	51 mg/g

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