



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

**Public Summary**

<b>Summary for ARTG Entry:</b>	202122	Magnesium-Diasporal
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Bio-Practica Pty Ltd	
<b>Postal Address</b>	651 Portrush Road, GLEN OSMOND, SA, 5064 Australia	
<b>ARTG Start Date</b>	22/10/2012	
<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.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

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 . Magnesium-Diasporal**

Product Type	Single Medicine Product	Effective Date	10/07/2019
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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
- 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)
- Decrease/reduce/relieve symptoms of mild anxiety
- Helps reduce occurrence of symptoms of mild anxiety
- Helps reduce occurrence of symptoms of headaches
- Decrease/reduce/relieve mild migraine symptoms
- Maintain/support nerve conduction

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Maintain/support nervous system health  
 Maintain/support nervous system function  
 Decrease/reduce/relieve menstrual spasms/cramps  
 Decrease/reduce/relieve menstruation pain/dysmenorrhoea  
 Decrease/reduce/relieve mood changes/mood swings associated with premenstrual tension  
 Decrease/reduce/relieve symptoms of premenstrual tension  
 Helps reduce occurrence of premenstrual tension symptoms  
 Decrease/reduce/relieve symptoms of menstruation  
 Maintain/support healthy pregnancy

**Indication Requirements**

Product presentation must only refer to mild anxiety.  
 Label statement: If symptoms persist, talk to your health professional.  
 Product presentation must not imply or refer to mental illnesses, disorders or conditions.

Product presentation must not imply or refer to serious cardiovascular 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 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.  
 Product presentation must not imply or refer to serious immunological diseases.  
 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 musculoskeletal or neurological 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).  
 Product presentation must only refer to mild migraine.  
 If directed to women, Label statement: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester.

**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**

<b>Dosage Form</b>	Powder, oral
<b>Route of Administration</b>	Oral

**Visual Identification**

**Active Ingredients**

<b>magnesium citrate</b>	<b>468.727 mg/g</b>
Equivalent: magnesium	72.727 mg/g

**Other Ingredients (Excipients)**

beet red  
 citric acid  
 Flavour  
 potassium bicarbonate

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riboflavin

Steviol glycosides

xylitol

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