Public Summary

Summary for ARTG Entry:	202122 Magnesium-Diasporal
ARTG entry for	Medicine Listed
Sponsor	Bio-Practica Pty Ltd
Postal Address	651 Portrush Road, GLEN OSMOND, SA, 5064 Australia
ARTG Start Date	22/10/2012
Product Category	Medicine
Status	Active
Approval Area	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

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

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

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 mental illnesses, disorders or conditions.

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

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

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 only refer to mild anxiety.

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.

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

Pack Size	Poison Schedule

Components

1 . Formulation 1

Dosage Form	Powder, oral
Route of Administration	Oral

Visual Identification

Active Ingredients

magnesium citrate	**468.727 mg/g**
Equivalent: magnesium	72.727 mg/g

Other Ingredients (Excipients)

beet red

citric acid

Flavour

potassium bicarbonate

riboflavin

Steviol glycosides

xylitol

Public Summary