



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

**Public Summary**

<b>Summary for ARTG Entry:</b>	330607	METAGENICS BIO ABSORB PEA
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Metagenics (Aust) Pty Ltd	
<b>Postal Address</b>	PO Box 675, VIRGINIA BC, QLD, 4014 Australia	
<b>ARTG Start Date</b>	2/03/2020	
<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.

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 . METAGENICS BIO ABSORB PEA**

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	2/03/2020
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**Permitted Indications**

- Anti-inflammatory/relieve inflammation
- Analgesic/Anodyne/relieve pain
- Decrease/reduce/relieve mild nerve pain/neuralgia

**Indication Requirements**

- Label statement: If symptoms persist, talk to your health professional.
- Product presentation must only refer to mild nerve pain/neuralgia.

**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

No Specific Indications included on Record

**Warnings**

- The medicine may interact with other prescription analgesic medicines, please consult your healthcare practitioner before use (or words to that effect)
- Not to be used for more than 21 consecutive days (or words to that effect)
- Adults only (or words to that effect).
- If symptoms persist consult your healthcare practitioner (or words to that effect).

**Additional Product information**

**Pack Size/Poison information**

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



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**1 . Formulation 1**

**Dosage Form** Capsule, hard  
**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

palmidrol 299.9997 mg

**Other Ingredients (Excipients)**

calcium hydrogen phosphate dihydrate  
chlorophyllin-copper complex  
colloidal anhydrous silica  
disodium edetate  
dl-alpha-tocopheryl acetate  
gellan gum  
hypromellose  
lecithin  
Lime Oil Coldpressed  
magnesium stearate  
medium chain triglycerides  
microcrystalline cellulose  
Olive Oil  
PEG-35 castor oil  
potassium acetate  
purified water  
silicon dioxide  
sorbitan monolaurate

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