



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

Public Summary

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

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

Product Type	Single Medicine Product	Effective Date	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

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

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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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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