



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	376653	METAGENICS BIO ABSORB PEA ADVANCED
<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>	21/10/2021	
<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 . METAGENICS BIO ABSORB PEA ADVANCED

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	21/10/2021
---------------------	-------------------------	-----------------------	------------

#### Permitted Indications

Anti-inflammatory/relieve inflammation  
Analgesic/Anodyne/relieve pain  
Aid/assist/helps synthesis of neurotransmitters  
Maintain/support nervous system function  
Decrease/reduce/relieve mild nerve pain/neuralgia

#### Indication Requirements

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 only refer to mild nerve pain/neuralgia.

#### Standard Indications

No Standard Indications included on Record

#### Specific Indications

No Specific Indications included on Record

#### Warnings

Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.  
The medicine may interact with other prescription analgesic medicines, please consult your healthcare practitioner before use.  
Adults only.  
If symptoms persist consult your healthcare practitioner (or words to that effect).  
Not to be used for more than 21 consecutive days.

#### Additional Product information

#### Pack Size/Poison information

<b>Pack Size</b>	<b>Poison Schedule</b>
------------------	------------------------

Public Summary



Australian Government  
Department of Health and Aged Care  
Therapeutic Goods Administration

**Components**

**1 . Formulation 1**

**Dosage Form** Capsule, hard

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

<b>Crocus sativus stigma Extract dry concentrate</b>	<b>7.5 mg</b>
Equivalent: Crocus sativus (Dry)	22.5 mg
<b>palmidrol</b>	<b>299.9997 mg</b>
<b>thiamine hydrochloride</b>	<b>50 mg</b>

**Other Ingredients (Excipients)**

calcium hydrogen phosphate dihydrate  
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  
potable water  
potassium acetate  
silicon dioxide

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary