



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	374580	PEA Supreme 300
ARTG entry for	Medicine Listed	
Sponsor	Designs For Health Pty Ltd	
Postal Address	1 / 418 Pittwater Road, North Manly, NSW, 2100 Australia	
ARTG Start Date	13/09/2021	
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.

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 . PEA Supreme 300

Product Type	Single Medicine Product	Effective Date	13/09/2021
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Permitted Indications

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

Adults only.

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.

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form	Capsule, hard
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Route of Administration	Oral
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Visual Identification

Active Ingredients

Public Summary



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palmidrol	299.9997 mg
quercetin dihydrate	30 mg

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
colloidal anhydrous silica
dl-alpha-tocopheryl acetate
hypromellose
lecithin
Lime Oil Coldpressed
magnesium stearate
medium chain triglycerides
microcrystalline cellulose
Olive Oil
PEG-35 castor oil
purified water
silicon dioxide

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