Public Summary

Summary for ARTG Entry:	380351 PEA Capsules
ARTG entry for	Medicine Listed
Sponsor	Bio Concepts Pty Ltd
Postal Address	PO Box 190, Banyo, Brisbane, QLD, 4014 Australia
ARTG Start Date	7/12/2021
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 Capsules

Product Type Single Medicine Product **Effective Date** 7/12/2021

Permitted Indications

Maintain/support general health and wellbeing

Anti-inflammatory/relieve inflammation

Analgesic/Anodyne/relieve pain

Decrease/reduce/relieve mild joint aches and pains

Decrease/reduce/relieve mild joint inflammation/swelling

Decrease/reduce/relieve mild joint pain/soreness

Decrease/reduce/relieve mild nerve pain/neuralgia

Indication Requirements

Product presentation must only refer to mild joint symptoms.

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

Product presentation must only refer to mild nerve pain/neuralgia.

Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Adults only.

The medicine may interact with other prescription analgesic medicines, please consult your healthcare practitioner before use.

Not to be used for more than 21 consecutive days.

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule

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Components

1 . Formulation 1

Dosage Form	Capsule, hard
Route of Administration	Oral
Visual Identification	

Active Ingredients

lecithin	**200 mg**
palmidrol	**300 mg**

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
colloidal anhydrous silica
hypromellose
leucine
microcrystalline cellulose
potable water

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