



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

## Public Summary

<b>Summary for ARTG Entry:</b>	422037	PainPlex
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Biomedica Nutraceuticals Pty Ltd	
<b>Postal Address</b>	PO Box 7052, ALEXANDRIA, NSW, 2015 Australia	
<b>ARTG Start Date</b>	19/09/2023	
<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 . PainPlex

Product Type	Single Medicine Product	Effective Date	2/02/2024
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#### Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Anti-inflammatory/relieve inflammation
- Traditionally used in Western herbal medicine to anti-inflammatory/relieve inflammation
- Traditionally used in Western herbal medicine to analgesic/Anodyne/relieve pain
- Traditionally used in Western herbal medicine to decrease/reduce/relieve mild joint aches and pains
- Traditionally used in Western herbal medicine to decrease/reduce/relieve mild rheumatic aches and pains
- Decrease/reduce/relieve symptoms of mild arthritis/mild osteoarthritis
  - Linked indication - Decrease/reduce/relieve mild joint inflammation/swelling
  - Linked indication - Decrease/reduce/relieve mild joint aches and pains
  - Linked indication - Decrease/reduce/relieve mild joint stiffness
  - Linked indication - Decrease/reduce/relieve mild joint pain/soreness
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of mild arthritis/mild osteoarthritis
- Decrease/reduce/relieve symptoms of mild arthritis/mild osteoarthritis
- Traditionally used in Western herbal medicine to decrease/reduce/relieve muscle pain/ache/soreness

#### Indication Requirements

- Product presentation must only refer to mild joint symptoms.
- Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.
- Label statement: If symptoms persist, talk to your health professional.
- Product presentation must only refer to mild rheumatic aches/pains.

#### Standard Indications

No Standard Indications included on Record

#### Specific Indications

No Specific Indications included on Record

#### Warnings

If symptoms persist consult a medical practitioner (or healthcare professional) (or words to that effect).

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Additional Product information

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

<b>Boswellia serrata gum Extract dry concentrate</b>	<b>50 mg</b>
Equivalent: Boswellia serrata (Dry)	700 mg
<b>Curcuma longa rhizome Extract dry concentrate</b>	<b>105.27 mg</b>
Equivalent: Curcuma longa (Dry)	6.8426 g
<b>Harpagophytum procumbens root Extract dry concentrate</b>	<b>150 mg</b>
Equivalent: Harpagophytum procumbens (Dry)	2.25 g
<b>Salix alba stem bark Extract dry concentrate</b>	<b>50 mg</b>
Equivalent: Salix alba (Dry)	1.625 g
<b>Zingiber officinale rhizome Extract dry concentrate</b>	<b>50 mg</b>
Equivalent: Zingiber officinale (Dry)	500 mg

Other Ingredients (Excipients)

Acacia  
calcium hydrogen phosphate dihydrate  
carrageenan  
colloidal anhydrous silica  
hypromellose  
maize starch  
maltodextrin  
Oryza sativa  
potassium acetate  
purified water  
Sunflower Oil

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