Public Summary

Summary for ARTG Entry:	227891 JOINT PLEX
ARTG entry for	Medicine Listed
Sponsor	The Pharmaceutical Plant Company Pty Ltd
Postal Address	3 Sigma Drive, Croydon South, VIC, 3136 Australia
ARTG Start Date	12/09/2014
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.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

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 . JOINT PLEX

Product Type	Single Medicine Product	**Effective Date**	20/06/2018

Permitted Indications

No Permitted Indications included on Record

Indication Requirements

No Indication Requirements included on Record

Standard Indications

No Standard Indications included on Record

Specific Indications

Joint Pain: Traditionally used in Western Herbal Medicine and Ayurvedic Medicine as an analgesic to assist with/ improve symptoms of/ relieve symptoms of/ soothe:
* joint pain associated with osteoarthritis
* joint aches associated with osteoarthritis
* osteoarthritic/ rheumatic pain

Joint Inflammation: Traditionally used in Western Herbal Medicine and Ayurvedic Medicine as an anti-inflammatory agent to assist with/ reduce:
* joint inflammation associated with osteoarthritis
* inflammatory joint conditions

Traditionally used in Western Herbal Medicine and Ayurvedic Medicine as an anti-rheumatic to assist in the management of arthritis/ osteoarthritis/ rheumatic conditions

Traditionally used in Western Herbal Medicine to assist in the management of gout

Traditionally used in Western Herbal Medicine and Ayurvedic Medicine for its anti-oxidant action

Traditionally used in Western Herbal Medicine as an analgesic to assist with/ improve symptoms of/ relieve symptoms of/ soothe lower back pain/ lumbago

Traditionally used in Western Herbal Medicine and Ayurvedic Medicine as a febrifuge to alleviate/ reduce fevers

Warnings

Contains ethanol. (or words to that effect).

If symptoms persist consult your healthcare practitioner (or words to that effect).

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule

Components

1 . Formulation 1

Dosage Form	Oral Liquid
Route of Administration	Oral
Visual Identification	

Active Ingredients

Apium graveolens	**100 microlitre/mL**
Equivalent: Apium graveolens	100 mg/mL
Curcuma longa	**150 microlitre/mL**
Equivalent: Curcuma longa	150 mg/mL
Harpagophytum procumbens	**225 microlitre/mL**
Equivalent: Harpagophytum procumbens	225 mg/mL
Salix alba	**150 microlitre/mL**
Equivalent: Salix alba	150 mg/mL

Other Ingredients (Excipients)

glycerol
Mentha X piperita
purified water

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