Public Summary

Summary for ARTG Entry:	234617 BLOOMS CELERY AND JUNIPER
ARTG entry for	Medicine Listed
Sponsor	Phytologic Holdings Pty Ltd
Postal Address	PO Box 6193, Alexandria, NSW, 2015 Australia
ARTG Start Date	6/03/2015
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 . BLOOMS CELERY AND JUNIPER

Product Type Single Medicine Product **Effective Date** 10/02/2021

Permitted Indications

Traditionally used in Western herbal medicine to temporarily relieve mild fluid retention

Maintain/support general health and wellbeing

Traditionally used in Western herbal medicine to decrease/reduce/relieve mild rheumatic aches and pains

Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of occasional episodes of gout

Traditionally used in Western herbal medicine to decrease/reduce/relieve mild joint pain/soreness

Traditionally used in Western herbal medicine to maintain/support healthy digestive system function

Traditionally used in Western herbal medicine to maintain/support healthy digestion

Traditionally used in Western herbal medicine to decrease/reduce/relieve nervous tension/unrest

Traditionally used in Western herbal medicine to calmative/nervous system relaxant

Traditionally used in Western herbal medicine to maintain/support urinary tract function

Traditionally used in Western herbal medicine to aid/assist flushing of the urinary tract

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. Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.

Product presentation must not imply or refer to mental illnesses, disorders or conditions.

Label statement: If symptoms persist, worsen or episodes become more frequent talk to your medical practitioner.

Product presentation must only refer to mild rheumatic aches/pains.

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

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

If fluid retention persists, seek medical advice (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	Capsule, hard
Route of Administration	Oral
Visual Identification	

Active Ingredients

Apium graveolens seed Extract dry concentrate	**300 mg**
Equivalent: Apium graveolens (Dry)	3 g
Juniperus communis fruit Extract dry concentrate	**200 mg**
Equivalent: Juniperus communis (Dry)	2 g

Other Ingredients (Excipients)

colloidal anhydrous silica
hypromellose
magnesium stearate
microcrystalline cellulose
purified water
silicon dioxide
sorbitol