



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	254632	Blooms Cranberry 35,000mg Plus
ARTG entry for	Medicine Listed	
Sponsor	Phytologic Holdings Pty Limited	
Postal Address	PO Box 6193, Alexandria, NSW, 2015 Australia	
ARTG Start Date	12/08/2015	
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.

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.

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 . Blooms Cranberry 35,000mg Plus

Product Type	Single Medicine Product	Effective Date	17/07/2020
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Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Maintain/support collagen formation
- Maintain/support connective tissue health
- Aid/assist/helps connective tissue production/formation
- Maintain/support bone health
- Help maintain/support bone mineralisation
- Helps maintain/supports healthy joint cartilage growth/development/production
- Maintain/support (state vitamin/mineral/nutrient) levels in the body
- Maintain/support general mental wellbeing
- Maintain/support skin health
- Maintain/support skin integrity/structure
- Maintain/support wound healing
- Maintain/support skin repair/healing/regeneration
- Helps reduce occurrence of medically diagnosed cystitis
- Maintain/support urinary tract health

Indication Requirements

- Product presentation must not imply or refer to mental illnesses, disorders or conditions.
- 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 only refer to medically diagnosed cystitis.
- Label statement: If pain or irritation persists for more than 48 hours, consult your doctor. The presence of blood in the urine warrants immediate medical attention (or words to that effect).

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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

No Warnings included on Record

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

ascorbic acid	50 mg
colloidal anhydrous silica	53.53 mg
Equivalent: silicon	25 mg
Vaccinium macrocarpon fruit Extract dry concentrate	50 mg
Equivalent: Vaccinium macrocarpon (Fresh)	30 g
Vaccinium macrocarpon fruit Extract dry concentrate	200 mg
Equivalent: Vaccinium macrocarpon (Fresh)	5 g

Other Ingredients (Excipients)

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

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