Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	349784	BLACKMORES CRANBERRY FORTE 50,000
ARTG entry for	Medicine Listed	
Sponsor	Blackmores Ltd	
Postal Address	PO Box 1725, WARRIEWOOD, NSW, 2102 Australia	
ARTG Start Date	26/11/2020	
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 . BLACKMORES CRANBERRY FORTE 50,000

Product Type	Single Medicine Product	**Effective Date**	26/11/2020

Permitted Indications

Antioxidant/Reduce free radicals formed in the body

Helps reduce occurrence of medically diagnosed cystitis

Maintain/support urinary tract health

Indication Requirements

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).

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

Vaccinium macrocarpon fruit Extract dry concentrate	**60 mg**
Equivalent: Vaccinium macrocarpon (Fresh)	30 g
Vaccinium macrocarpon fruit Extract dry concentrate	**400 mg**
Equivalent: Vaccinium macrocarpon (Fresh)	20 g

Other Ingredients (Excipients)

calcium phosphate
colloidal anhydrous silica
disodium edetate
gellan gum
hypromellose
magnesium hydroxide
magnesium stearate
microcrystalline cellulose
potable water
potassium acetate

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