



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	347564	Cystitum
ARTG entry for	Medicine Listed	
Sponsor	McPherson's Consumer Products Pty Ltd	
Postal Address	Locked Bag 5018, Kingsgrove, NSW, 2208 Australia	
ARTG Start Date	6/11/2020	
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 . Cystitum

Product Type	Single Medicine Product	Effective Date	6/11/2020
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Permitted Indications

- Traditionally used in Chinese medicine to clear/expel damp-heat from the bladder
- Traditionally used in Western herbal medicine to anti-inflammatory/relieve inflammation
- Traditionally used in Western herbal medicine to demulcent/soothe irritated tissues
- Helps reduce occurrence of medically diagnosed cystitis in females
- Traditionally used in Chinese medicine to helps decrease/reduce/relieve burning sensation/irritation upon urination associated with medically diagnosed cystitis in/of Bladder Damp Heat pattern
- Traditionally used in Chinese medicine to helps decrease/reduce/relieve symptoms of medically diagnosed cystitis in/of Bladder Damp Heat pattern
- Traditionally used in Western herbal medicine to helps decrease/reduce/relieve symptoms of medically diagnosed cystitis
- Traditionally used in Chinese medicine to helps decrease/reduce/relieve symptoms of medically diagnosed cystitis
- Traditionally used in Chinese medicine to maintain/support urinary tract health in/of Bladder Damp Heat pattern
- Traditionally used in Chinese medicine to maintain/support urinary tract function in/of Bladder Damp Heat pattern
- Traditionally used in Western herbal medicine to aid/assist flushing of the urinary tract
- Traditionally used in Chinese medicine to maintain/support healthy urine output in/of Bladder Damp Heat pattern

Indication Requirements

- Label statement: If symptoms persist, talk to your health professional.
- Product presentation must not imply or refer to kidney disease.
- 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).
- Product presentation must only refer to medically diagnosed cystitis.
- Product presentation must not imply or refer to disease in any body organ.
- If TCM terminology is used on medicine label, label statement: Talk to a TCM practitioner/health professional if you are unsure if this medicine is right for you.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

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Warnings

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).

Additional Product information

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Tablet, film coated

Route of Administration Oral

Visual Identification

Active Ingredients

Alisma orientale root Extract dry concentrate	100 mg
Equivalent: Alisma orientale (Dry)	1 g
Crateva magna stem bark Extract dry concentrate	50 mg
Equivalent: Crateva magna (Dry)	500 mg
Elymus repens rhizome Extract dry concentrate	200 mg
Equivalent: Elymus repens (Dry)	2 g
Phellodendron amurense stem bark Extract dry concentrate	50 mg
Equivalent: Phellodendron amurense (Dry)	500 mg
Pyrrosia shearerii whole plant Extract dry concentrate	100 mg
Equivalent: Pyrrosia shearerii (Dry)	1 g
Vaccinium macrocarpon fruit Extract dry concentrate	83.3 mg
Equivalent: Vaccinium macrocarpon (Fresh)	4.165 g

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate

Carnauba Wax

colloidal anhydrous silica

croscarmellose sodium

hypromellose

macrogol 400

magnesium stearate

maltodextrin

microcrystalline cellulose

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