



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	315941	METAGENICS KIDNEY CARE
ARTG entry for	Medicine Listed	
Sponsor	Metagenics (Aust) Pty Ltd	
Postal Address	PO Box 675, VIRGINIA BC, QLD, 4014 Australia	
ARTG Start Date	29/03/2019	
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 . METAGENICS KIDNEY CARE

Product Type	Single Medicine Product	Effective Date	29/03/2019
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Permitted Indications

Antioxidant/Reduce free radicals formed in the body

Traditionally used in Western herbal medicine to help maintain/support body's natural channels of elimination

Maintain/support (state vitamin/mineral) within normal range

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

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

Traditionally used in Western herbal medicine to maintain/support kidney health

Traditionally used in Western herbal medicine to maintain/support healthy urine output

Indication Requirements

Product presentation must not imply or refer to disease in any body organ, in particular the kidney or liver.

Product presentation must not imply or refer to kidney disease.

Product presentation must not imply or refer to drugs/alcohol.

Product presentation must only refer to detoxification in relation to natural body processes.

Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record



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Warnings

Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet. 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 Tablet, film coated

Route of Administration Oral

Visual Identification

Active Ingredients

d-alpha-tocopheryl acid succinate	83 mg
Equivalent: d-alpha-tocopherol	100 IU
Equisetum arvense herb Extract dry concentrate	50 mg
Equivalent: Equisetum arvense (Dry)	500 mg
Galium aparine herb Extract dry concentrate	150 mg
Equivalent: Galium aparine (Dry)	3 g
pyridoxine hydrochloride	12.5 mg
Equivalent: pyridoxine	10 mg
quercetin dihydrate	119 mg
Equivalent: quercetin	100 mg
thiamine hydrochloride	15 mg
Zea mays stigma and style Extract dry concentrate	500 mg
Equivalent: Zea mays (Dry)	2 g

Other Ingredients (Excipients)

croscarmellose sodium
ethylcellulose
hypolose
macrogol 8000
microcrystalline cellulose
silicon dioxide
stearic acid

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