



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	305536	Kidney Complex
ARTG entry for	Medicine Listed	
Sponsor	FIT-BioCeuticals Limited	
Postal Address	Care of Blackmores Ltd PO Box 1725, Warriewood, NSW, 2102 Australia	
ARTG Start Date	28/06/2018	
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 . Kidney Complex

Product Type	Single Medicine Product	Effective Date	4/07/2018
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Permitted Indications

- Maintain/support body electrolyte balance
- Traditionally used in Western herbal medicine to temporarily relieve mild fluid retention
- Traditionally used in Western herbal medicine to decrease/reduce/relieve mild joint aches and pains
- 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 mild arthritis/mild osteoarthritis
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of occasional episodes of gout
- Helps decrease/reduce homocysteine levels
- Helps enhance/promote/increase body utilisation of (state mineral/vitamin/nutrient)
- Traditionally used in Western herbal medicine to aid/assist flushing of the urinary tract

Indication Requirements

- Label statement: If symptoms persist, talk to your health professional.
- 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.
- Label statement: If symptoms persist, worsen or episodes become more frequent talk to your medical practitioner.
- Label statement: If fluid retention persists, seek medical advice (or words to that effect).
- Product presentation must only refer to mild fluid retention.
- Product presentation must only refer to mild joint symptoms.
- Product presentation must not imply or refer to cardiovascular or renal conditions.

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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).

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

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
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Components

1 . Formulation 1

Dosage Form Tablet, film coated

Route of Administration Oral

Visual Identification

Active Ingredients

Apium graveolens seed Extract dry concentrate	62.5 mg
Equivalent: Apium graveolens (Dry)	375 mg
calcium folinate	108 microgram
Equivalent: folic acid	100 microgram
hydroxocobalamin	50 microgram
magnesium citrate nonahydrate	105.14 mg
Equivalent: magnesium	12.5 mg
menaquinone 7	.0225 mg
potassium citrate	69.14 mg
Equivalent: potassium	25 mg
Prunus cerasus fruit flesh Powder	60 mg
Equivalent: Prunus cerasus (Fresh)	1.5 g
pyridoxal 5-phosphate monohydrate	19.6 mg
Equivalent: pyridoxine	12.5 mg
Terminalia bellirica fruit pericarp Extract dry concentrate	125 mg
Equivalent: Terminalia bellirica (Dry)	412.5 mg

Other Ingredients (Excipients)

- ascorbyl palmitate
- calcium hydrogen phosphate dihydrate
- Candelilla Wax
- Carnauba Wax
- chlorophyllin-copper complex
- colloidal anhydrous silica
- crospovidone
- hypromellose
- macrogol 400
- maltodextrin
- microcrystalline cellulose
- povidone
- yellow beeswax

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