Public Summary

Summary for ARTG Entry:	370390	Gout 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	30/06/2021	
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 . Gout Complex

Product Type Single Medicine Product **Effective Date** 30/06/2021

Permitted Indications

Traditionally used in Western herbal medicine to aids/assists excretion of metabolic waste products

Traditionally used in Western herbal medicine to temporarily relieve mild fluid retention

Maintain/support general health and wellbeing

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

Traditionally used in Western herbal medicine to decrease/reduce/relieve mild joint pain/soreness

Helps decrease/reduce homocysteine levels

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

Traditionally used in Western herbal medicine to aid/assist flushing of the urinary tract

Indication Requirements

Product presentation must not imply or refer to cardiovascular or renal conditions.

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.

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

Label statement: If fluid retention persists, seek medical advice (or words to that effect).

Product presentation must only refer to mild joint symptoms.

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

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

Product presentation must only refer to mild fluid retention.

Label statement: If symptoms persist, worsen or episodes become more frequent talk to your medical practitioner.

Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.

Product presentation must not imply or refer to kidney disease.

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

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	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: folinic acid	100 microgram
hydroxocobalamin	**50 microgram**
magnesium citrate nonahydrate	**105.13 mg**
Equivalent: magnesium	12.5 mg
menaquinone 7	**.0225 mg**
potassium citrate	**69.13 mg**
Equivalent: potassium	25 mg
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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