



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	273857	Gout Fighter Plus
ARTG entry for	Medicine Listed	
Sponsor	Nature's Sunshine Products of Australia Pty Ltd	
Postal Address	PO Box 6884, BAULKHAM HILLS BUSINESS CENTRE, NSW, 2153 Australia	
ARTG Start Date	5/04/2016 11:00:00 PM	
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 Fighter Plus

Product Type	Single Medicine Product	Effective Date	28/04/2023
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Permitted Indications

Traditionally used in Western herbal medicine to anti-inflammatory/relieve inflammation

Traditionally used in Western herbal medicine to analgesic/Anodyne/relieve pain

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 occasional episodes of gout

Linked indication - Decrease/reduce/relieve mild joint aches and pains

Linked indication - Decrease/reduce/relieve mild joint inflammation/swelling

Linked indication - Decrease/reduce/relieve mild joint pain/soreness

Traditionally used in Western herbal medicine to helps reduce the occasional occurrence of symptoms of gout

Traditionally used in Western herbal medicine to enhance/promote/increase urine output

Indication Requirements

Label statement: If symptoms persist, talk to your health professional.

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

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

Product presentation must not imply or refer to kidney disease.

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 joint symptoms.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

If symptoms persist consult your healthcare practitioner (or words to that effect).

Additional Product information



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

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	300 mg
Equivalent: Apium graveolens (Dry)	3 g
Prunus cerasus fruit Extract dry concentrate	440 mg
Equivalent: Prunus cerasus (Fresh)	11 g
Salix alba stem bark Extract dry concentrate	45 mg
Equivalent: Salix alba (Dry)	4.5 g

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
Carnauba Wax
colloidal anhydrous silica
croscarmellose sodium
crospovidone
hypromellose
iron oxide black
iron oxide red
macrogol 8000
magnesium stearate
maltodextrin
microcrystalline cellulose
povidone
titanium dioxide

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