



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

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|--------------------------------|---|---------------------|
| Summary for ARTG Entry: | 374670 | Gout Relief Complex |
| ARTG entry for | Medicine Listed | |
| Sponsor | Herbs of Gold Pty Ltd | |
| Postal Address | PO Box 3143, KIRRAWEE, NSW, 2232 Australia | |
| ARTG Start Date | 15/09/2021 | |
| 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 Relief Complex

| | | | |
|---------------------|-------------------------|-----------------------|-----------|
| Product Type | Single Medicine Product | Effective Date | 6/07/2022 |
|---------------------|-------------------------|-----------------------|-----------|

Permitted Indications

Antioxidant/Reduce free radicals formed in the body

Anti-inflammatory/relieve inflammation

Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of occasional episodes of gout

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, worsen or episodes become more frequent talk to your medical practitioner.

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

Product presentation must not imply or refer to kidney disease.

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

Pack Size/Poison information

| | |
|------------------|------------------------|
| Pack Size | Poison Schedule |
|------------------|------------------------|

Components

1 . Formulation 1

| | |
|--------------------------------|---------------|
| Dosage Form | Capsule, hard |
| Route of Administration | Oral |



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Visual Identification

Active Ingredients

| | |
|--|-----------------|
| Apium graveolens seed Extract dry concentrate | 75 mg |
| Equivalent: Apium graveolens (Dry) | 1.5 g |
| magnesium citrate | 52.43 mg |
| Equivalent: magnesium | 8.1 mg |
| Medicago sativa leaf Extract dry concentrate | 75 mg |
| Equivalent: Medicago sativa (Dry) | 375 mg |
| potassium citrate | 50.06 mg |
| Equivalent: potassium | 18.1 mg |
| Terminalia bellirica fruit pericarp Extract dry concentrate | 250 mg |
| Equivalent: Terminalia bellirica (Dry) | 1 g |

Other Ingredients (Excipients)

colloidal anhydrous silica
hypromellose
magnesium stearate
maltodextrin
microcrystalline cellulose
purified water

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