



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	25680	Nature's Sunshine Herbal Diuretic
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	15/10/1991	
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.

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 . Nature's Sunshine Herbal Diuretic

Product Type	Single Medicine Product	Effective Date	6/08/2020
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Permitted Indications

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

Traditionally used in Western herbal medicine to decrease/reduce/relieve flatulence/carminative

Traditionally used in Western herbal medicine to helps decrease/reduce/relieve symptoms of medically diagnosed cystitis

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

Indication Requirements

Label statement: If pain or irritation persists for more than 48 hours, consult your doctor. The presence of blood in the urine warrants immediate medical attention (or words to that effect).

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

Product presentation must only refer to medically diagnosed cystitis.

Product presentation must only refer to mild fluid retention.

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

Product presentation must not imply or refer to kidney disease.

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

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

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Pack Size/Poison information

Pack Size **Poison Schedule**

Components

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

Arctostaphylos uva-ursi leaf Powder	81.8 mg
Juniperus communis fruit Powder	104.3 mg
Matricaria chamomilla flower Powder	54.8 mg
Petroselinum crispum leaf Powder	97.7 mg
Taraxacum officinale root Powder	76.4 mg

Other Ingredients (Excipients)

Gelatin

glacial acetic acid

potable water

silicon dioxide

sodium lauryl sulfate

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