



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	252574	Thursday Plantation Aloe Vera Gel
ARTG entry for	Medicine Listed	
Sponsor	Integria Healthcare Australia Pty Ltd	
Postal Address	PO Box 4854, EIGHT MILE PLAINS, QLD, 4113 Australia	
ARTG Start Date	4/08/2015	
Product Category	Medicine	
Status	Active	
Approval Area	Listed Medicines	

Conditions

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 . Thursday Plantation Aloe Vera Gel

Product Type	Single Medicine Product	Effective Date	10/05/2019
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Permitted Indications

Antioxidant/Reduce free radicals formed in the body
Helps reduce/decrease free radical damage to body cells
Anti-inflammatory/relieve inflammation
Decrease/reduce/relieve skin dryness
Soothe skin
Soothe/relieve skin inflammation
Helps decrease/reduce/relieve symptoms of minor skin wounds (cuts, scratches and abrasions)
Helps healing of mild skin burn/sunburns
Soothe/relieve mild skin burn/sunburns
Antimicrobial for minor cuts and abrasions
Maintain/support wound healing
Maintain/support skin repair/healing/regeneration

Indication Requirements

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

If product is indicated for skin burn, Label statement: Only to be used for minor burns after initial first aid treatment, medical advice should be sought for serious burns.

Product presentation must only refer to 'mild' burns.

If product is indicated for skin burn, Label statement: Immediate treatment of burns should be application of cold water for ten minutes (or words to that effect).

Product presentation must not imply or refer to serious infections.

Standard Indications



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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).

Contains hydroxybenzoates (or words to this effect) if the medicines contains more than one hydroxybenzoate source OR Contains (insert the approved name of hydroxybenzoate used)(or words to this effect) if product contains one hydroxybenzoate source.

Contains benzoates' (or words to this effect) if the medicine contains two or more benzoate sources or 'Contains [insert the approved name of benzoate used]' (or words to this effect) if product contains one benzoate source.

Contains sorbates' (or word to this effect) if medicine contains two or more sorbate sources OR 'Contains [insert the approved name of sorbate source used]' (or words to this effect) if medicine contains one sorbate source.

Contains diazolidinylurea (or words to that effect).

Additional Product information

Pack Size/Poison information

Pack Size **Poison Schedule**

Components

1 . Formulation 1

Dosage Form Gel
Route of Administration Topical

Visual Identification

Active Ingredients

Aloe vera leaf inner juice Juice concentrate	97.624 mg/g
Equivalent: Aloe vera (Juice fresh)	974.28 mg/g

Other Ingredients (Excipients)

- allantoin
- brilliant blue FCF
- carbomer 940
- citric acid
- diazolidinyl urea
- disodium edetate
- methyl hydroxybenzoate
- potassium sorbate
- propyl hydroxybenzoate
- propylene glycol
- purified water
- quinoline yellow
- sodium benzoate
- sodium chloride
- sodium hydroxide
- sodium sulfate
- sunset yellow FCF

Public Summary

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