



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	354466	WELEDA BURNS & BITES COOLING GEL
ARTG entry for	Medicine Listed	
Sponsor	Weleda Australia Pty Ltd	
Postal Address	Unit 2 92A Mona Vale Road, Warriewood, Sydney, NSW, 2102 Australia	
ARTG Start Date	8/02/2021	
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.

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 . WELEDA BURNS & BITES COOLING GEL

Product Type	Single Medicine Product	Effective Date	18/02/2021
---------------------	-------------------------	-----------------------	------------

Permitted Indications

Traditionally used in Western herbal medicine to relieve hot skin
Traditionally used in Western herbal medicine to soothe/relieve skin inflammation
Traditionally used in Western herbal medicine to decrease/reduce/relieve skin irritation
Traditionally used in Western herbal medicine to antipruritic/Relieves itchy skin
Traditionally used in Western herbal medicine to helps healing of mild skin burn/sunburns
Traditionally used in Western herbal medicine to soothe/relieve mild skin burn/sunburns
Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of insect bite/sting

Indication Requirements

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

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 only refer to 'mild' burns.

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.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

For the treatment of burns, immediate treatment should consist of the rapid application of cold water for a suitable period and the product should only be applied later [or words to that effect] the product is for the first-aid treatment of minor burns only and medical advice should be sought for the treatment of more serious burns [Or words to that effect].

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

Contains ethanol or contains alcohol.

Additional Product information

Container information



Australian Government
Department of Health
Therapeutic Goods Administration

Type	Material	Life Time	Temperature	Closure	Conditions
Tube	Not recorded	Not recorded	Not recorded	Not recorded	Not recorded

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 Dry	1 mg/g
Equivalent: Aloe vera (Fresh)	200 mg/g
Arnica montana flower Tincture	4.5 mg/g
Equivalent: Arnica montana (Dry)	450 microgram/g
Arnica montana root Tincture	500 microgram/g
Equivalent: Arnica montana (Dry)	50 microgram/g
Echinacea purpurea whole plant Tincture	25 mg/g
Equivalent: Echinacea purpurea (Fresh)	8.3 mg/g
Urtica urens herb top Tincture	95 mg/g
Equivalent: Urtica urens (Fresh)	47.5 mg/g

Other Ingredients (Excipients)

ethanol
glycerol
purified water
sodium alginate

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary