



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	354465	WELEDA HYPERCAL HEALING CREAM
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 HYPERCAL HEALING CREAM

Product Type	Single Medicine Product	Effective Date	18/02/2021
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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 soothe skin
Traditionally used in Western herbal medicine to helps enhance/promote skin regeneration
Traditionally used in Western herbal medicine to helps decrease/reduce/relieve symptoms of minor skin wounds (cuts, scratches and abrasions)
Traditionally used in Western herbal medicine to vulnery/wound healing
Traditionally used in Western herbal medicine to antimicrobial for minor cuts and abrasions
Traditionally used in Western herbal medicine to antiseptic for minor cuts and abrasions
Traditionally used in Western herbal medicine to maintain/support wound healing
Traditionally used in Western herbal medicine to enhance/improve/promote skin repair/healing
Traditionally used in Western herbal medicine to maintain/support skin repair/healing/regeneration

Indication Requirements

Product presentation must not imply or refer to serious infections.
Label statement: If symptoms persist, talk to your health professional.

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
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Components

1 . Formulation 1



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Dosage Form Cream

Route of Administration Topical

Visual Identification

Active Ingredients

Calendula officinalis flower Extract liquid	225 mg/g
Equivalent: Calendula officinalis (Dry)	22.5 mg/g
Calendula officinalis flower Infusion	135 mg/g
Equivalent: Calendula officinalis (Dry)	13.5 mg/g
Calendula officinalis whole plant Tincture	50 mg/g
Equivalent: Calendula officinalis (Fresh)	10 mg/g
Hypericum perforatum whole plant Tincture	50 mg/g
Equivalent: Hypericum perforatum (Fresh)	16.7 mg/g
Hypericum perforatum herb flowering Infusion	135 mg/g
Equivalent: Hypericum perforatum (Dry)	13.5 mg/g
Hypericum perforatum flower Extract liquid	150 mg/g
Equivalent: Hypericum perforatum (Fresh)	30 mg/g

Other Ingredients (Excipients)

glycerol
Lavender Oil
lecithin
Simmondsia chinensis
sodium alginate
Vitellaria paradoxa
yellow beeswax

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