



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	66830 WELEDA ARNICA 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	11/11/1998
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 ARNICA CREAM

Product Type	Single Medicine Product	Effective Date	18/02/2021
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Permitted Indications

- Traditionally used in Western herbal medicine to decrease/reduce/relieve mild joint aches and pains
- Traditionally used in Western herbal medicine to aid/assist/helps in the healing of minor muscle injuries
- Traditionally used in Western herbal medicine to reduce/decrease mild muscle inflammation
- Traditionally used in Western herbal medicine to helps decrease/reduce/relieve symptoms of muscle sprain/strain
- Traditionally used in Western herbal medicine to decrease/reduce/relieve muscle pain/ache/soreness
- Traditionally used in Western herbal medicine to enhance/improve/promote healing of bruises
- Traditionally used in Western herbal medicine to decrease/reduce/relieve bruise pain

Indication Requirements

- Product presentation must only refer to mild joint symptoms.
- Label statement: If symptoms persist, talk to your health professional.
- Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.

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).
- Contains ethanol or contains alcohol.

Additional Product information

Container information

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
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Components

1 . Formulation 1

Dosage Form Cream

Route of Administration Topical

Visual Identification

Active Ingredients

Abies pectinata leaf Oil essential	600 microgram/g
Arnica montana flower Extract liquid	200 mg/g
Equivalent: Arnica montana (Dry)	20 mg/g
Arnica montana root Tincture	30 mg/g
Equivalent: Arnica montana (Dry)	3 mg/g
Arnica montana flower Tincture	270 mg/g
Equivalent: Arnica montana (Dry)	27 mg/g
Lemon Oil Distilled	2 mg/g
Orange Oil	1 mg/g
Rosemary Oil	2.1 mg/g
Sage Oil Spanish	300 microgram/g

Other Ingredients (Excipients)

Almond oil
glycerol
lecithin
purified water
self-emulsifying glyceryl monostearate
sesame oil
Tragacanth
yellow beeswax

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