



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	99952	BRAUER ARNICAEZE ARNICA GEL
ARTG entry for	Medicine Listed	
Sponsor	Brauer Natural Medicine Pty Ltd	
Postal Address	PO Box 234, TANUNDA, SA, 5352 Australia	
ARTG Start Date	2/03/2004	
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 . BRAUER ARNICAEZE ARNICA GEL

Product Type	Single Medicine Product	Effective Date	1/09/2022
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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 decrease/reduce/relieve symptoms of muscle injury/ailments

Traditionally used in Western herbal medicine to helps decrease/reduce/relieve symptoms of muscle sprain/strain

Traditionally used in Western herbal medicine to enhance/improve/promote healing of bruises

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

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 ethanol or contains alcohol.

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form	Gel
Route of Administration	Topical

Visual Identification

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Active Ingredients

Arnica montana herb flowering Tincture	100 mg/g
Equivalent: Arnica montana (Dry)	10 mg/g

Other Ingredients (Excipients)

brilliant blue FCF
carbomer 940
dl-alpha-tocopherol
imidurea
isopropyl alcohol
methyl hydroxybenzoate
PEG-7 glyceryl cocoate
polysorbate 20
purified water
trolamine

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