



**Australian Government**  
**Department of Health**  
 Therapeutic Goods Administration

**Public Summary**

<b>Summary for ARTG Entry:</b>	99952	BRAUER ARNICAEZE ARNICA GEL
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Brauer Natural Medicine Pty Ltd	
<b>Postal Address</b>	PO Box 234, TANUNDA, SA, 5352 Australia	
<b>ARTG Start Date</b>	2/03/2004	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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**

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	15/02/2021
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**Permitted Indications**

- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve mild joint aches and pains
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve mild joint pain/soreness
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve muscle pain/ache/soreness
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve bruise pain

**Indication Requirements**

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

**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

No Specific Indications included on Record

**Warnings**

Contains ethanol or contains alcohol.  
 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.

**Additional Product information**

**Pack Size/Poison information**

<b>Pack Size</b>	<b>Poison Schedule</b>
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**Components**

**1 . Formulation 1**

**Dosage Form** Gel

**Route of Administration** Topical

**Visual Identification**

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**Active Ingredients**

<b>Arnica montana herb flowering Tincture</b>	<b>100 mg/g</b>
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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