



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

## Public Summary

<b>Summary for ARTG Entry:</b>	152670	Traumeel Gel
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Brauer Professional Pty Ltd	
<b>Postal Address</b>	PO Box 174, GLEN OSMOND, SA, 5064 Australia	
<b>ARTG Start Date</b>	28/05/2008	
<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.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

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 . Traumeel Gel

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	11/08/2020
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### Permitted Indications

- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve symptoms of soft tissue trauma
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve symptoms of mild arthritis/mild osteoarthritis
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve mild joint inflammation/swelling
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve mild joint pain/soreness
- Decrease/reduce/relieve symptoms of muscle injury/ailments
- Helps decrease/reduce/relieve symptoms of muscle sprain/strain
- Traditionally used in Homoeopathic medicine to helps decrease/reduce/relieve symptoms of muscle sprain/strain
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve muscle pain/ache/soreness
- Decrease/reduce/relieve muscle pain/ache/soreness
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve bruise pain
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve bruise swelling

### Indication Requirements

Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis. Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.

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 homoeopathic ingredients.

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



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Contains ethanol or contains alcohol.

**Additional Product information**

**Pack Size/Poison information**

**Pack Size**

**Poison Schedule**

**Components**

**1 . Formulation 1**

**Dosage Form** Gel  
**Route of Administration** Topical

**Visual Identification**

**Active Ingredients**

<b>Achillea millefolium herb flowering Tincture</b>	<b>900 microgram/g</b>
Equivalent: Achillea millefolium (Fresh)	300 microgram/g
<b>Aconitum napellus whole plant (Homeopathic)</b>	<b>500 microgram/g</b>
Equivalent: Total alkaloids (of Aconitum spp.)	160 ng/g
<b>Arnica montana root and rhizome (Homeopathic)</b>	<b>15 mg/g</b>
<b>Atropa belladonna whole plant (Homeopathic)</b>	<b>500 microgram/g</b>
Equivalent: Alkaloids calculated as hyoscyamine	50 ng/g
Equivalent: atropine	12.5 ng/g
<b>Bellis perennis whole plant Tincture</b>	<b>1 mg/g</b>
Equivalent: Bellis perennis (Fresh)	500 microgram/g
<b>calcium sulfide (Homeopathic)</b>	<b>250 microgram/g</b>
<b>Calendula officinalis herb flowering Tincture</b>	<b>4.5 mg/g</b>
Equivalent: Calendula officinalis (Fresh)	1.5 mg/g
<b>Echinacea angustifolia whole plant Tincture</b>	<b>1.5 mg/g</b>
Equivalent: Echinacea angustifolia (Fresh)	500 microgram/g
<b>Echinacea purpurea herb flowering Tincture</b>	<b>1.5 mg/g</b>
Equivalent: Echinacea purpurea (Fresh)	500 microgram/g
<b>hahnemann's soluble mercury (Homeopathic)</b>	<b>400 microgram/g</b>
<b>Hamamelis virginiana stem bark Tincture</b>	<b>4.5 mg/g</b>
Equivalent: Hamamelis virginiana (Fresh)	1.5 mg/g
<b>Hypericum perforatum whole plant (Homeopathic)</b>	<b>900 microgram/g</b>
<b>Matricaria chamomilla whole plant Tincture</b>	<b>1.5 mg/g</b>
Equivalent: Matricaria chamomilla (Fresh)	500 microgram/g
<b>Symphytum officinale root and rhizome (Homeopathic)</b>	<b>1 mg/g</b>

**Other Ingredients (Excipients)**

carbomer 980  
 ethanol absolute  
 purified water  
 sodium hydroxide

Public Summary

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