



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

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

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

Product Type	Single Medicine Product	Effective Date	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
- Traditionally used in Homoeopathic medicine to helps decrease/reduce/relieve symptoms of muscle sprain/strain
- 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

- 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. 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.
- 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.
- Contains ethanol or contains alcohol.

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

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

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

Other Ingredients (Excipients)

carbomer 980
ethanol absolute
purified water
sodium hydroxide

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