



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

**Public Summary**

<b>Summary for ARTG Entry:</b>	273827	Zen Sports Spray
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Martin & Pleasance Pty Ltd	
<b>Postal Address</b>	PO Box 2007, SOUTH MELBOURNE, VIC, 3205 Australia	
<b>ARTG Start Date</b>	4/04/2016 11:00:00 PM	
<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.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

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 . Zen Sports Spray**

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	22/01/2020
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**Permitted Indications**

- Traditionally used in Chinese medicine to invigorate/activate Blood
- Traditionally used in Chinese medicine to analgesic/Anodyne/relieve pain
- Traditionally used in Chinese medicine to decrease/reduce/relieve mild joint inflammation/swelling
- Traditionally used in Chinese medicine to decrease/reduce/relieve mild joint inflammation/swelling
- Traditionally used in Chinese medicine to helps enhance/promote healthy blood circulation
- Aid/assist/helps in the healing of minor muscle injuries
- Traditionally used in Chinese medicine to aid/assist/helps in the healing of minor muscle injuries
- Traditionally used in Chinese medicine to reduce/decrease mild muscle inflammation
- Traditionally used in Chinese medicine to reduce/decrease mild muscle inflammation
- Aid/assist/helps in the management of muscle sprain/strain
- Traditionally used in Chinese medicine to aid/assist/helps in the management of muscle sprain/strain
- Traditionally used in Chinese medicine to helps decrease/reduce/relieve symptoms of muscle sprain/strain
- Helps decrease/reduce/relieve symptoms of muscle sprain/strain
- Traditionally used in Chinese medicine to decrease/reduce/relieve muscle pain/ache/soreness
- Decrease/reduce/relieve muscle pain/ache/soreness
- Traditionally used in Chinese medicine to enhance/improve/promote healing of bruises
- Enhance/improve/promote healing of bruises
- Traditionally used in Chinese 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.

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Label statement: If symptoms persist, talk to your health professional.

Product presentation must only refer to mild joint symptoms.

Product presentation must not imply or refer to serious cardiovascular conditions.

If TCM terminology is used on medicine label, label statement: Talk to a TCM practitioner/health professional if you are unsure if this medicine is right for you.

**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

No Specific Indications included on Record

**Warnings**

Contains ethanol or contains alcohol.

**Additional Product information**

**Pack Size/Poison information**

**Pack Size**

**Poison Schedule**

**Components**

**1 . Formulation 1**

**Dosage Form** Spray

**Route of Administration** Topical

**Visual Identification**

**Active Ingredients**

<b>Arnica montana flower Extract liquid</b>	<b>140 microlitre/mL</b>
Equivalent: Arnica montana (Dry)	20 mg/mL
<b>Boswellia carterii stem bark resin Extract liquid</b>	<b>110 microlitre/mL</b>
Equivalent: Boswellia carterii (Dry)	15.714 mg/mL
<b>Commiphora myrrha stem bark resin Extract liquid</b>	<b>100 microlitre/mL</b>
Equivalent: Commiphora myrrha (Dry)	14.286 mg/mL
<b>Mentha arvensis herb Oil essential</b>	<b>100 mg/mL</b>
<b>Panax pseudoginseng root Extract liquid</b>	<b>110 microlitre/mL</b>
Equivalent: Panax pseudoginseng (Dry)	15.714 mg/mL

**Other Ingredients (Excipients)**

camphor

ethanol

glycerol

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