



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	322664	Zen Sports Roll-On
ARTG entry for	Medicine Listed	
Sponsor	Martin & Pleasance Pty Ltd	
Postal Address	PO Box 2007, SOUTH MELBOURNE, VIC, 3205 Australia	
ARTG Start Date	4/09/2019	
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.

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 Roll-On

Product Type	Single Medicine Product	Effective Date	4/09/2019
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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 maintain/support 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 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
- 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
 - Linked indication - Decrease/reduce/relieve mild joint inflammation/swelling
 - Linked indication - Decrease/reduce/relieve bruise swelling
 - Linked indication - Decrease/reduce/relieve bruise pain
- Helps decrease/reduce/relieve symptoms of muscle sprain/strain
 - Linked indication - Decrease/reduce/relieve muscle pain/ache/soreness
 - Linked indication - Decrease/reduce/relieve bruise swelling
- Decrease/reduce/relieve muscle pain/ache/soreness
- Traditionally used in Chinese medicine to decrease/reduce/relieve muscle pain/ache/soreness
- Enhance/improve/promote healing of bruises
- Traditionally used in Chinese medicine to enhance/improve/promote healing of bruises
- Traditionally used in Chinese medicine to decrease/reduce/relieve bruise swelling

Indication Requirements

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

Product presentation must only refer to mild joint symptoms.

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.

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 not imply or refer to serious cardiovascular conditions.

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
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Components

1 . Formulation 1

Dosage Form	Gel
Route of Administration	Topical

Visual Identification

Active Ingredients

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

Other Ingredients (Excipients)

- camphor
- ethanol
- glycerol
- polyacrylate crosspolymer-6
- purified water
- tert-butyl alcohol

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