



Australian Government

Department of Health
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

Athletes Gel Pty Ltd

for approval to supply

Athletes Gel

ARTG Identifier AUST L 295444
ARTG Start date 24/10/2017
Product type Listed Medicine

| Manufacturer Details | Address | Manufacturing Steps |
|--|--|--|
| Australian Laboratory Services Pty Ltd | Unit 10 2-8 South Street RYDALMERE, NSW, 2116 Australia | Testing microbial Testing chemical and physical |
| Chemical Analysis Pty Ltd | 110 Merrindale Drive CROYDON SOUTH, VIC, 3136 Australia | Testing microbial Testing chemical and physical |
| Finishing Services Pty Ltd | 286 Chesterville Road MOORABBIN, VIC, 3189 Australia | Secondary packaging |
| Lipa Pharmaceuticals Ltd | 21 Reaghs Farm Road MINTO, NSW, 2566 Australia | Testing microbial Testing chemical and physical |
| TSI Pharmaceuticals Pty Ltd | 262 Evans Road SALISBURY, QLD, 4107 Australia | Secondary packaging Testing chemical and physical Release for supply Packaging and labelling Manufacture of dosage form |
| Wesley Community Services Ltd | 211 Victoria Road DUNDAS, NSW, 2117 Australia | Secondary packaging |

ARTG Standard Conditions

The above Medicine Listed has been entered on the Register subject to the following 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 Covered by This Entry

1. Athletes Gel

Product Specific Conditions

No specific conditions have been recorded against this entry.

Product Standard Indications

No standard indications have been recorded against this entry.

Product Specific Indications

- (Capsicum, Arnica and Wintergreen Oil have been) Traditionally used in Western Herbal medicine to help relieve muscle pain/ aches/ soreness (associated with sports performance & recovery, overuse, muscular sprains and strains, and other mild muscular traumas.)
- Capsicum, Arnica and Wintergreen Oil are known for their analgesic (pain relieving) properties
- (Capsicum/ Capsaicin) May help to relieve pain associated with mild osteoarthritis
- (Capsicum, Arnica and Wintergreen Oil have been) Traditionally used in Western Herbal Medicine as an analgesic (to assist with/ relieve the symptoms of/ soothe muscle pain/ aches/ soreness) (associated with sports performance & recovery, overuse, muscular sprains and strains, and rheumatism)
- (Capsicum, Arnica and Wintergreen Oil have been) Traditionally used in Western Herbal Medicine to help relieve stiffness, mild inflammation, pain and swelling of the joints (associated with mild arthritis.)
- (Capsicum, Arnica and Wintergreen Oil have been) Traditionally used in Western Herbal Medicine to help relieve mild inflammation of the muscles/ muscular inflammation
- Experimental studies have found Capsicum, Arnica, and Clove bud oil to have anti-inflammatory properties
- Arnica is used in traditional Western Herbal Medicine to help relieve symptoms of musculoskeletal sprains, strains and bruising
- Traditionally used in Western Herbal Medicine to assist with/ to help relieve symptoms of muscle fatigue (associated with sports performance and recovery and overuse).
- (Capsicum and Arnica have been) Traditionally used in Western Herbal Medicine as a counter-irritant/ rubefacient (to improve/ stimulate circulation and improve blood supply) (and help relieve muscle and joint pain).

Warnings

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

Dosage Form

Gel

Route of Administration

- Topical

Visual Identification

Not recorded

Additional Product information

Product Formulation(s)

Active Ingredients

| | Quantity | Units |
|--------------------------|----------|-------|
| Clove Bud Oil | 100 | mg/g |
| Wintergreen Oil | 300 | mg/g |
| Capsicum fruit oleoresin | 7.7 | mg/g |
| Arnica montana | 15 | mg/g |