Public Summary

Summary for ARTG Entry:	168983 Bioeffective (R) Gel
ARTG entry for	Medicine Listed
Sponsor	Prenolica Ltd
Postal Address	98 - 106 Moray Street, SOUTH MELBOURNE, VIC, 3205 Australia
ARTG Start Date	11/02/2010
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 . Bioeffective (R) Gel

Product Type Single Medicine Product **Effective Date** 24/08/2010

Permitted Indications

No Permitted Indications included on Record

Indication Requirements

No Indication Requirements included on Record

Standard Indications

For the symptomatic relief of minor wounds (cuts, scratches, abrasions).

For the symptomatic relief of minor burns (including sunburn).

Specific Indications

Conifer Green Needle Complex (Bioeffective A) possesses potent antioxidant properties. Antioxidants are nutrients which reduce the risk of cell damage attributed to free radicals.
Traditionally used to help promote healing of minor wounds (cuts-scratches- abrasions) and minor skin irritations such as minor burns (including sunburn).

Warnings

For external use only.

Contains ethanol. (or words to that effect).

Contains phenoxyethanol (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	
Aloe vera	**3.5 mg/mL**
Equivalent: Aloe vera	700 mg/mL
Conifer green needle complex	**75 mg/mL**

Other Ingredients (Excipients)

acetylated monoglycerides
carbomer 940
d-alpha-tocopheryl acetate
disodium edetate
ethanol absolute
glycerol
maltodextrin
menthol
Olea europaea
phenoxyethanol
polysorbate 20
purified water
Soya Oil

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