Public Summary

Summary for ARTG Entry: 294245  Feel Good Inc. Sticky Zinc SPF50+ Sunscreen Cream

- ARTG entry for Medicine Listed
- Sponsor: Baxter Laboratories Pty Ltd
- Postal Address: 1019 Mountain Highway, BORONIA, VIC, 3155, Australia
- ARTG Start Date: 22/09/2017
- 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. Feel Good Inc. Sticky Zinc SPF50+ Sunscreen Cream

- Product Type: Single Medicine Product
- Effective date: 22/09/2017

Permitted Indications

- No Permitted Indications included on Record

Indication Requirements

- No Indication Requirements included on Record

Standard Indications

- Broad Spectrum Sunscreen
- A broad spectrum sunscreening preparation of SPF50+. Can aid in the prevention of sunspots
- A broad spectrum sunscreening preparation of SPF50+. Can aid in the prevention of solar keratoses
- A broad spectrum sunscreening preparation of SPF50+. May reduce the risk of some skin cancers
- A broad spectrum sunscreening preparation of SPF50+. May assist in preventing some skin cancers
- Sunscreen SPF50 Plus

Specific Indications

- No Specific Indications included on Record

Warnings

- Avoid prolonged exposure in the sun. [or words to that effect]
- Wear protective clothing, hats and eyewear when exposed to the sun. [Or words to this effect]

Additional Product information

Container information

- Type
- Material
- Life Time
- Temperature
- Closure
- Conditions

This is not an ARTG Certificate document.
The onus is on the reader to verify the current accuracy of the information on the document subsequent to the date shown.
<table>
<thead>
<tr>
<th>Pack Size/Poison information</th>
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<tbody>
<tr>
<td>Pack Size</td>
<td>Poison Schedule</td>
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<td>Components</td>
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<td>Dosage Form</td>
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