Australian Government

Department of Health

Therapeutic Goods Administration

**Record Summary** 227282 98 Alive Immune

| | |
|---|---|
| **Sponsor** | 98 Alive Pty Ltd |
| **Therapeutic Type** | Medicine |
| **Product Category** | Listed |
| **ARTG Start date** | 26/08/2014 |
| **Postal Address** | [redacted] |
| **Billing Address** | |

**Conditions**

Colouring agents used in listed medicine for ingestion, other than those listed for export only under section 25 of the Act, shall be only hose included in the list of 'Colourings permitted in medicines for oral use'.

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 he 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 han those accepted in relation to the inclusion of the medicine in he 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 mon hs 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.

**Manufacturers**

| Name | Address | Manufacturing steps |
|---|---|---|
| [redacted] | | |

Record Summary

[redacted]

## Products

### 1.98 Alive Immune

**Product Type** Single Medicine Product

**Status** Current

**Effective date** 26/08/2014

**Permitted Indications**

No Permitted Indications included on Record

**Indication Requirements**

No Indication Requirements included on Record

**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

Supports a healthy immune system
Antioxidant

**Warnings**

ZINC WARNING: May be dangerous if taken in large amounts or for a long period. OR WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).

No Warnings included on Record

**Specific Conditions**

**Components**

**1.**

**Dosage form** Capsule, hard

**Route of Administration** Oral

**Maximum daily dose** 2

**Weight of divided preparation** 720 mg

**Formulations**

| Active Ingredients | Category | Quantity | Units |
|---|---|---|---|
| **Melaleuca alternifolia** | **AHN** | **150** | **mg** |
| **Plant details (origin)** | **Part** | **Preparation** | |
| | leaf | Oil essential | |
| **Equivalent** | | | |
| Melaleuca Oil | | 145.2 | mg |
| cineole | | 3.6 | microgram |
| Cajuput Oil | | 0 | microgram |
| **zinc amino acid chelate** | **AAN** | **75** | **mg** |
| **Equivalent** | | | |
| zinc | | 15 | mg |

| Excipient Ingredients | Category | Quantity | Units |
|---|---|---|---|
| **Empty Gelatin Capsules Size 00 White Op White Op (PI 12969)** | **PI** | | |
| **microcrystalline cellulose** | **AAN** | | |
| **silicon dioxide** | **AAN** | | |

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