

Australian Government

Department of Health

Therapeutic Goods Administration

| Record Summary | 235279 | 98 Alive Immune Support | | |
|------------------|------------------|-------------------------|--|--|
| Sponsor | 98 Alive Pty Ltd | | | |
| Therapeutic Type | Medicine | | | |
| Product Category | Listed | | | |
| ARTG Start date | 20/03/2015 | | | |
| Postal Address | | | | |
| 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.

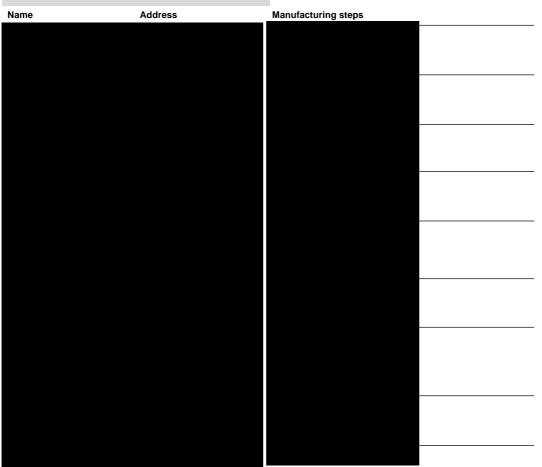
The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other han those accepted in relation to the inclusion of the medicine in he Register.

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



Page 1 of 2

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The details contained in this copy of the Record Summary reflect the information held at the nominated date and ime of printing The currency and accuracy of the details can be confirmed at www.ebs.gov au."

1.98 Alive Immune Support

| Product Type | Single Medicine Product |
|--------------|-------------------------|

Status

Current

Effective date 20/0

20/03/2015

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

VIT

Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.

No Warnings included on Record

Specific Conditions

| Components | | | | |
|-------------------------|---------------|--|--|--|
| • | | | | |
| 1. | | | | |
| | | | | |
| Dosage form | Capsule, hard | | | |
| - | • | | | |
| Route of Administration | Oral | | | |
| | 0 rai | | | |
| Weight of divided | 745 mg | | | |
| weight of ulvided | 745 mg | | | |

preparation Formulations

| Active Ingredients | Category | Quantity | Units |
|--------------------------------|----------|---------------|-----------|
| betacarotene (from PI 108632) | AAN | 3 | mg |
| calcium ascorbate | AAN | 120 | mg |
| Melaleuca alternifolia | AHN | 150 | mg |
| Concentration ratio | 1: | | |
| Plant details (origin) | Part | Preparation | |
| | leaf | Oil essential | |
| Equivalent | | | |
| Cajuput Oil | | 0 | microgram |
| cineole | | 3.6 | microgram |
| Melaleuca Oil | | 145.2 | mg |

| Excipient Ingredients | Category | Quantity | Units |
|---|----------|----------|-------|
| Empty Gelatin Capsules Size 00 White Op White Op (PI 12969) | PI | | |
| Lyc-O-Beta 20% VBAF (PI 108632) | PI | 15 | mg |
| microcrystalline cellulose | AAN | | |
| silicon dioxide | AAN | | |