

# **Australian Government**

# **Department of Health**

# Therapeutic Goods Administration

Record Summary

Sponsor

Therapeutic Type
Product Category
ARTG Start date
Postal Address

285406
98 Alive Pty Ltd
Medicine
Listed
8/02/2017

### Conditions

**Billing Address** 

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.

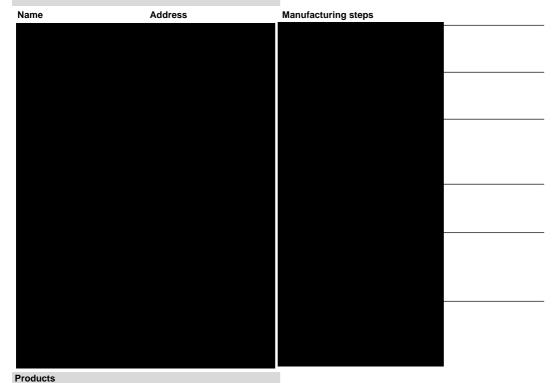
The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other han those accepted in relation to the inclusion of the medicine in he Register.

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



## 1.98 Alive Immune Syrup

 Product Type
 Single Medicine Product
 Status
 Current

 Effective date
 8/02/2017

# **Indication Requirements**

No Indication Requirements included on Record

# **Standard Indications**

No Standard Indications included on Record

### **Specific Indications**

Used to assist immune system strength

# 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
 Oral Liquid

 Route of Administration
 Oral

 Maximum daily dose
 7 mL

# **Formulations**

Active Ingredients	Category	Quantity	Units
betacarotene	AAN	3	mg/mL
calcium ascorbate	AAN	8	mg/mL
Melaleuca alternifolia	AHN	10	microlitre/mL
Plant details (origin)	Part	Preparation	
	leaf	Oil essential	
Equivalent			
Melaleuca Oil		9.68	mg/mL
cineole		120	microgram/mL

Excipient Ingredients	Category	Quantity	Units
glycerol	AAN	70	mg/mL
purified water	AAN		
Strawberry Flavour TM656099 (PI 111161)	PI	.5	microlitre/mL
sucrose	AAN	6	mg/mL
xanthan gum	AAN		

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