



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	[Redacted]	
Billing Address	[Redacted]	

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 those 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 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.

Manufacturers

Name	Address	Manufacturing steps
[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]

Record Summary

The details contained in this copy of the Record Summary reflect the information held at the nominated date and time 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 20/03/2015

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
Weight of divided preparation 745 mg

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		

Record Summary