Australian Government

Department of Health

Therapeutic Goods Administration

Record Summary

Record Summary 285406 98 Alive Immune Syrup

Sponsor	98 Alive Pty Ltd
Therapeutic Type	Medicine
Product Category	Listed
ARTG Start date	8/02/2017
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]		

Products

1.98 Alive Immune Syrup

Product Type	Single Medicine Product	**Status**	Current
		Effective date	8/02/2017

Record Summary

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

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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