Australian Government

Department of Health

Therapeutic Goods Administration

Record Summary 279838 98Alive Nasal Spray

Sponsor	98 Alive Pty Ltd
Therapeutic Type	Medicine
Product Category	Listed
ARTG Start date	2/09/2016
Postal Address	[redacted]
Billing Address	

Conditions

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

1.98Alive Nasal Spray

Product Type	Single Medicine Product	**Status**	Current
		Effective date	2/09/2016

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

May assist in the management of inflammation associated with cold, mild influenza, hayfever and allergies.
98Alive Nasal Spray has been specifically formulated for the symptomatic relief of stuffy and blocked noses

Warnings

COLD	Adults only. OR Not to be used in children under two years of age without medical advice (or words to that effect).

Record Summary

Produced at 29.04.2020 at 03:58:37 AEST

S If symptoms persist consult your healthcare practitioner (or words to that effect).

No Warnings included on Record

Specific Conditions

Components

1.

Dosage form Spray, nasal

Route of Administration Nasal

Formulations

Active Ingredients	Category	Quantity	Units
Melaleuca alternifolia	**AHN**	**10**	**mg/mL**
Plant details (origin)	**Part**	**Preparation**	
	leaf	Oil essential	
Equivalent			
cineole		120	microgram/mL
Melaleuca Oil		9.68	mg/mL
Cajuput Oil		0	mg/mL

Excipient Ingredients	Category	Quantity	Units
purified water	**AAN**		
sodium chloride	**AAN**		

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