



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	362437	METAGENICS ALERGEZE
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Metagenics (Aust) Pty Ltd	
<b>Postal Address</b>	PO Box 675, VIRGINIA BC, QLD, 4014 Australia	
<b>ARTG Start Date</b>	19/04/2021	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	Listed Medicines	

### 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.

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.

### Products

#### 1 . METAGENICS ALERGEZE

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	19/04/2021
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#### Permitted Indications

Maintain/support digestion/assimilation of nutrients  
Aid/assist/helps digestion of (state nutrient)  
Decrease/reduce/relieve symptoms of hayfever  
Decrease/reduce/relieve symptoms of allergic rhinitis  
Decongestant/relieve nasal congestion  
Unblock/clear nasal passages  
Decrease/reduce/relieve sneezing  
Helps decrease/reduce/relieve nasal itching  
Relieve runny/dripping nose

#### Indication Requirements

Label statement: If symptoms persist, talk to your health professional.

Label statement: Adults only, OR Not to be used in children under 2 years of age without medical advice (or words to that effect).

#### Standard Indications

No Standard Indications included on Record

#### Specific Indications

No Specific Indications included on Record

#### Warnings

Adults only. OR Not to be used in children under two years of age without medical advice (or words to that effect).  
If symptoms persist consult your healthcare practitioner (or words to that effect).

#### Additional Product information

#### Pack Size/Poison information

<b>Pack Size</b>	<b>Poison Schedule</b>
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Components

1 . Formulation 1

Dosage Form                      Tablet, film coated

Route of Administration        Oral

Visual Identification

Active Ingredients

<b>Albizia lebeck stem bark Extract dry concentrate</b>	<b>23.56 mg</b>
Equivalent: Albizia lebeck (Dry)	188.5 mg
<b>bromelains</b>	<b>9 million PU</b>
<b>Phyllanthus emblica fruit pericarp Extract dry concentrate</b>	<b>78.28 mg</b>
Equivalent: Phyllanthus emblica (Dry)	391.38 mg
<b>Piper longum fruit Extract dry concentrate</b>	<b>11.06 mg</b>
Equivalent: Piper longum (Dry)	15.48 mg
<b>Piper nigrum fruit Extract dry concentrate</b>	<b>7.06 mg</b>
Equivalent: Piper nigrum (Dry)	14.83 mg
<b>quercetin dihydrate</b>	<b>500 mg</b>
<b>Terminalia bellirica fruit pericarp Extract dry concentrate</b>	<b>75.9 mg</b>
Equivalent: Terminalia bellirica (Dry)	379.5 mg
<b>Terminalia chebula fruit pericarp Extract dry concentrate</b>	<b>128.7 mg</b>
Equivalent: Terminalia chebula (Dry)	643.5 mg
<b>Zingiber officinale rhizome Extract dry concentrate</b>	<b>5.45 mg</b>
Equivalent: Zingiber officinale (Dry)	14.7 mg

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate  
Carnauba Wax  
colloidal anhydrous silica  
croscarmellose sodium  
hypromellose  
macrogol 400  
magnesium stearate  
maltodextrin  
microcrystalline cellulose  
potassium hydroxide  
sodium hydroxide

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