



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

## Public Summary

<b>Summary for ARTG Entry:</b>	407405	Arborvitae ModeX
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Arborvitae Health and Wellbeing Pty Ltd	
<b>Postal Address</b>	6 Ellesmere Avenue, Hunters Hill, NSW, 2110 Australia	
<b>ARTG Start Date</b>	5/04/2023 11:00:00 PM	
<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 . Arborvitae ModeX

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	6/04/2023
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#### Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Maintain/support physical endurance/capacity/stamina
- Helps enhance/promote general health and wellbeing
- Maintain/support general health and wellbeing
- Anti-inflammatory/relieve inflammation
- Helps enhance/promote healthy blood circulation
- Maintain/support healthy blood circulation
- Maintain/support immune system health
- Maintain/support healthy immune system function
- Decrease/reduce/relieve muscle cramps
- Decrease/reduce/relieve muscle pain/ache/soreness
- Helps enhance/improve/promote/increase muscle performance/endurance/stamina
- Aid/assist/helps post exercise recovery
- Helps enhance/improve/promote/increase physical/exercise performance
- Helps enhance/improve/promote/increase attention span
- Maintain/support mental concentration/focus/clarity
- Enhance/improve/promote/increase cognitive performance
- Maintain/support cognitive function/mental function
- Maintain/support memory/mental recall

#### Indication Requirements

- Product presentation must not imply or refer to mental illnesses, disorders or conditions.
- Label statement: If symptoms persist, talk to your health professional.
- Product presentation must not imply or refer to chronic fatigue syndrome.
- Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.
- Product presentation must not imply or refer to serious immunological diseases.
- Product presentation must not imply or refer to serious cardiovascular conditions.



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**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

No Specific Indications included on Record

**Warnings**

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

(If medicine contains one sugar) contains [insert name of sugar] OR (If medicine contains two or more sugars) Contains sugars [or words to that effect].

Not suitable for infants under the age of twelve months (or words to that effect).

Contains sorbates' (or word to this effect) if medicine contains two or more sorbate sources OR 'Contains [insert the approved name of sorbate source used]' (or words to this effect) if medicine contains one sorbate source.

Contains benzoates' (or words to this effect) if the medicine contains two or more benzoate sources or 'Contains [insert the approved name of benzoate used]' (or words to this effect) if product contains one benzoate source.

**Additional Product information**

**Pack Size/Poison information**

Pack Size	Poison Schedule
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**Components**

**1 . Formulation 1**

**Dosage Form** Oral Liquid

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

<b>Aloe vera leaf inner Juice dry</b>	<b>1.75 mg/mL</b>
Equivalent: Aloe vera (Fresh)	350 mg/mL
<b>papain</b>	<b>2.4 mg/mL</b>
<b>Pinus pinaster stem bark Dry</b>	<b>2 mg/mL</b>
Equivalent: Pinus pinaster (Dry)	2000 mg/mL
<b>sodium chloride</b>	<b>3 mg/mL</b>
Equivalent: sodium	1.181 mg/mL

**Other Ingredients (Excipients)**

anthocyanins

Flavour

glacial acetic acid

Honey

maltodextrin

potassium sorbate

purified water

sodium benzoate

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