



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

## Public Summary

<b>Summary for ARTG Entry:</b>	285193	Alpha CRS+
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	doTERRA Australia Pty Ltd	
<b>Postal Address</b>	Ground Floor, 350 Wellington Road, MULGRAVE, VIC, 3170 Australia	
<b>ARTG Start Date</b>	3/02/2017	
<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.

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.

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.

The Ginkgo biloba leaf extract used in the manufacture of this medicine must comply with the requirement of Identification Test B of the monograph Powdered Ginkgo Extract in the United States Pharmacopeia 32 - National Formulary 27 (USP32-NF27) as in force or existing from time to time. This condition does not apply to powdered or dried leaf.

### Products

#### 1 . Alpha CRS+

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	8/07/2020
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#### Permitted Indications

Antioxidant/Reduce free radicals formed in the body  
Maintain/support energy production  
Maintain/support general health and wellbeing

#### Indication Requirements

If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.

#### Standard Indications

No Standard Indications included on Record

#### Specific Indications

No Specific Indications included on Record

#### Warnings

Do not take while on warfarin therapy without medical advice.

#### Additional Product information

#### Pack Size/Poison information

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

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**1 . Formulation 1**

**Dosage Form** Capsule, hard  
**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

<b>acetyl levocarnitine hydrochloride</b>	<b>29.48 mg</b>
<b>alpha lipoic acid</b>	<b>25 mg</b>
<b>Boswellia serrata gum oleoresin Extract dry concentrate standardised</b>	<b>76.92 mg</b>
Equivalent: Boswellia serrata (Dry)	461.54 mg
<b>bromelains</b>	<b>4.17 mg</b>
<b>Camellia sinensis leaf Extract dry concentrate standardised</b>	<b>9.04 mg</b>
Equivalent: Camellia sinensis (Dry)	271.2 mg
<b>Carum carvi seed Extract dry concentrate</b>	<b>2.5 mg</b>
Equivalent: Carum carvi (Dry)	10 mg
<b>curcumin</b>	<b>7.89 mg</b>
<b>Ginkgo biloba leaf Extract dry concentrate standardised</b>	<b>200 microgram</b>
Equivalent: Ginkgo biloba (Dry)	10 mg
<b>Mentha X piperita leaf Extract dry concentrate</b>	<b>2.5 mg</b>
Equivalent: Mentha X piperita (Dry)	10 mg
<b>Pinus pinaster</b>	<b>2.61 mg</b>
<b>Punica granatum seed Extract dry concentrate</b>	<b>15.63 mg</b>
Equivalent: Punica granatum (Dry)	781.25 mg
<b>quercetin dihydrate</b>	<b>12.5 mg</b>
<b>Reynoutria japonica root Extract dry concentrate standardised</b>	<b>25 mg</b>
Equivalent: Reynoutria japonica (Dry)	2.5 g
<b>Scutellaria baicalensis root Extract dry concentrate</b>	<b>44.12 mg</b>
Equivalent: Scutellaria baicalensis (Dry)	573.53 mg
<b>Sesamum indicum seed Extract dry concentrate</b>	<b>5 mg</b>
Equivalent: Sesamum indicum (Dry)	20 mg
<b>Silybum marianum fruit Extract dry concentrate standardised</b>	<b>31.25 mg</b>
Equivalent: Silybum marianum (Dry)	2.1875 g
<b>ubidecarenone</b>	<b>12.5 mg</b>
<b>Vitis vinifera seed Extract dry concentrate standardised</b>	<b>5.2632 mg</b>
Equivalent: Vitis vinifera (Dry)	631.58 mg
<b>Zingiber officinale root Extract dry concentrate</b>	<b>2.5 mg</b>
Equivalent: Zingiber officinale (Dry)	50 mg

**Other Ingredients (Excipients)**

calcium hydrogen phosphate dihydrate  
carrageenan  
colloidal anhydrous silica  
croscarmellose sodium  
glucose monohydrate  
hypromellose  
magnesium stearate  
maltodextrin  
microcrystalline cellulose  
potassium acetate  
purified water  
soy polysaccharide

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