

Department of Health

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: Lifelong Vitality Pack 337774

ARTG entry for Medicine Listed

Sponsor doTERRA Australia Pty Ltd

Postal Address 102 / 271 Wellington Road, Mulgrave, VIC, 3170

ARTG Start Date 12/06/2020 **Product Category** Medicine Status Active

Listed Medicines Approval Area

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 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.

Products

1. Lifelong Vitality Pack

Product Type **Effective Date** 8/07/2020 Medicine Kit

Permitted Indications

No Permitted Indications included on Record

Indication Requirements

No Indication Requirements included on Record

Standard Indications

No Standard Indications included on Record

Indications

BDAOB-S-RD Antioxidant/reduce free radicals formed in the body.

IMHEF-G-MS Maintain/support healthy immune system function.

IMHE-G-MS Maintain/support immune system health.

BDGHW-G-MS Maintain/support general health and wellbeing.

BDENFO-S-CN Helps convert (Fats and Carbohydrates) into energy.

BDENP-S-MS Maintain/support energy production. BDHRH-G-MS Maintain/support hair health.

BDNAH-G-MS Maintain/support nail health/strength/thickness.

NUVMMT-S-AA Aid/assist/helps metabolism of (Carbohydrates, Fats & Proteins).

SKSTH-G-MS Maintain/support skin health.

NUVMDF-S-PV Helps prevent dietary Biotin, Magnesium, Calcium, Vitamin C, Folate, Pantothenic acid, Chromium, Vitamin D, Copper, Vitamin B12,

Vitamin E, Niacin, Vitamin K, Pyridoxine, Vitamin A, Riboflavin, Selenium, Thiamine, Zinc, Omega-3 fatty acid deficiency.

BOHE-S-MS Maintain/support bone health.

CVH-G-MS Maintain/support cardiovascular system health.
CVHEFU-G-MS Maintain/support healthy cardiovascular system function.

CVHEHE-G-MS Maintain/support heart health.

BDEN-G-MS Maintain/support energy levels.

MUHF-G-MS Maintain/support muscle function. NVHSY-G-MS Maintain/support nervous system health.

NVHSYFU-G-MS Maintain/support nervous system function. NVHCN-S-MS Maintain/support nerve conduction.

MUHNE-G-MS Maintain/support healthy neuromuscular system/function.

BOHEST-G-MS Maintain/support bone strength.

BOHMN-S-MS Help maintain/support bone mineralisation.

BOHEM-S-MS Maintain/support bone mass/density/integrity.

BOJOARC-S-PV A diet deficient in calcium can lead to osteoporosis in later life. Calcium may help prevent osteoporosis when dietary intake is inadequate.



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GIDIF-G-MS Maintain/support healthy digestive system function.

GIDIH-G-MS Maintain/support healthy digestion

MUHCN-G-MS Maintain/support healthy muscle contraction function.

NVHNMF-S-MS Maintain/support neuromuscular function.

BDCOF-S-MS Maintain/support collagen formation.

BDTSC-G-MS Maintain/support connective tissue health.
BDTSCT-S-AA Aid/assist/helps connective tissue production/formation.

CVVCAF-S-MS Maintain/support blood capillary health.

CVVEH-S-MS Maintain/support blood vessel health.

NVHNTSY-S-AA Aid/assist/helps synthesis of neurotransmitters.

NUVMAB-S-MS Maintain/support absorption of dietary Iron.

SKWOHL-G-MS Maintain/support wound healing.

CVBCRCP-S-AA Aid/assist healthy red blood cell production.

NUVMMT-S-AA Aid/assist/helps metabolism of (proteins)

NUNUPR-S-AA Aid/assist/helps protein synthesis in the body.

NVAXADEN-G-AA Aids/assists the body to cope with environmental stress.

NVAXADSTRE-G-MS Support healthy stress response in the body.

NUNUGM-S-AA Aid/assist/helps glucose/sugar/carbohydrate metabolism.

NUVMMT-S-AA Aid/assist/helps metabolism of (Carbohydrate, Lipid and Protein).

BOJOAVD-S-PV Vitamin D helps calcium absorption (or words of like intent) and a diet deficient in calcium can lead to osteoporosis in later life.

NUVMAB-S-MS Maintain/support absorption of dietary (Calcium and Phosphorus).

NUVMBL-S-MS Maintain/support (Calcium) levels in the body.

NUVMBL-S-MS Maintain/support (Vitamin D) levels in the body when sun exposure is inadequate.

NUVMBL-S-MS Maintain/support (Vitamin D) levels in the body in elderly individuals when sun exposure is inadequate.

BDCOH-S-MS Maintain/support collagen health.

CVBRCH-S-MS Helps maintain/support haemoglobin formation/synthesis.

NUVMMT-S-AA Aid/assist/helps metabolism of Iron.

CVBLHE-G-MS Maintain/support blood health.

CVBLOX-S-MS Helps maintain/support transport of oxygen in the body.

CVBLOXT-S-AA Aid/assist/helps oxygen transport to body tissues.

BDENFO-S-CN Helps convert (food) into energy.

SKSTRIN-G-MS Maintain/support skin integrity/structure.

BDTSH-G-MS Maintain/support healthy body tissues.

CVBCRH-S-MS Maintain/support red blood cell health.

BDHRG-G-MS Maintain/support hair growth.

BDNAH-G-MS Maintain/support nail health/strength/thickness.

BDNAG-G-AA Aid/assist nail growth.

ENDTHPR-S-AA Aid/assist thyroid hormone production.

ENDTHHO-S-MS Maintain/support healthy thyroid hormones.

ENDTHFU-G-MS Maintain/support healthy thyroid gland function. NVBRCGFU-G-MS Maintain/support cognitive function/mental function.

SKSTRIN-G-MS Maintain/support skin integrity/structure.

SKSTRRG-G-MS Maintain/support skin regeneration.

BDEYHE-G-MS Maintain/support eye health.

BDEYHRET-S-MS Helps maintain/support eye retina health.

BDEYVI-G-MS Maintain/support healthy eyesight/vision.

NVBRFN-G-MS Maintain/support brain function.

Warnings

Do not take while on warfarin therapy without medical advice.

This medicine contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.

(If medicine contains one benzoate) Contains [insert name of benzoate] Or (If medicine contains two or more benzoates) Contains benzoates [or words to that effect].

Additional Product information

Pack Size/Poison information

Pack Size Poison Schedule

Components

1 . xEO Mega (ARTG: 327961) 2 . Alpha CRS+ (ARTG: 285193) 3 . Microplex VMz (ARTG: 336370)

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Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 336370 Microplex VMz

ARTG entry for Medicine Listed

Sponsor doTERRA Australia Pty Ltd

Postal Address 102 / 271 Wellington Road, Mulgrave, VIC, 3170

Australia

ARTG Start Date 14/05/2020
Product Category Medicine
Status Active

Approval Area 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.

Products

1. Microplex VMz

Product Type Single Medicine Product Effective Date 14/05/2020

Permitted Indications

Antioxidant/Reduce free radicals formed in the body

Maintain/support collagen formation

Maintain/support collagen health

Maintain/support energy levels

Helps convert (state food) into energy

Maintain/support energy production

Maintain/support general health and wellbeing

Maintain/support hair growth

Maintain/support hair health

Aid/assist nail growth

Maintain/support nail health/strength/thickness

Maintain/support connective tissue health

Aid/assist/helps connective tissue production/formation

Maintain/support healthy body tissues

Maintain/support bone health

Maintain/support bone mass/density/integrity

Maintain/support bone strength

Help maintain/support bone mineralisation

A diet deficient in calcium can lead to osteoporosis in later life. Calcium may help prevent osteoporosis when dietary intake is inadequate

Vitamin D helps calcium absorption (or words of like intent) and a diet deficient in calcium can lead to osteoporosis in later life

Aid/assist healthy red blood cell production

Maintain/support red blood cell health

Maintain/support blood health



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Helps maintain/support transport of oxygen in the body

Aid/assist/helps oxygen transport to body tissues

Helps maintain/support haemoglobin formation/synthesis

Maintain/support cardiovascular system health

Maintain/support healthy cardiovascular system function

Maintain/support heart health

Maintain/support blood capillary health

Maintain/support blood vessel health

Maintain/support healthy thyroid gland function

Maintain/support healthy thyroid hormones

Aid/assist thyroid hormone production

Maintain/support healthy digestive system function

Maintain/support immune system health

Maintain/support healthy immune system function

Maintain/support healthy muscle contraction function

Maintain/support muscle function

Maintain/support healthy neuromuscular system/function

Aid/assist/helps glucose/sugar/carbohydrate metabolism

Aid/assist/helps protein synthesis in the body

Maintain/support absorption of dietary (state vitamin/mineral/nutrient)

Maintain/support (state vitamin/mineral/nutrient) levels in the body when sun exposure is inadequate

Maintain/support (state vitamin/mineral/nutrient) levels in the body when sun exposure is inadequate in elderly individuals

Maintain/support (state vitamin/mineral/nutrient) levels in the body

Helps prevent dietary (state vitamin/mineral/nutrient) deficiency

Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)

Aids/assists the body to cope with environmental stress

Support healthy stress response in the body

Maintain/support cognitive function/mental function

Maintain/support nerve conduction

Maintain/support neuromuscular function

Aid/assist/helps synthesis of neurotransmitters

Maintain/support nervous system health

Maintain/support nervous system function

Maintain/support skin health

Maintain/support skin integrity/structure

Maintain/support skin regeneration

Maintain/support wound healing

Indication Requirements

Product presentation must not imply or refer to mental illnesses, disorders or conditions.

Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.

Product presentation must not imply or refer to circulatory disorders/diseases/conditions e.g. thrombosis.

Product presentation must not imply or refer to serious cardiovascular conditions.

Product presentation must not imply or refer to heart disease.

Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis. Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.

Indication can only be used for medicines that contain calcium as an active ingredient and the recommended daily dose of the medicine must provide at least 290 milligrams of elemental calcium.

Indication only for use for medicines that contain vitamin D as an active ingredient. The medicines may only contain a maximum recommended daily dose of 25 micrograms or less of vitamin D and as a minimum, also contain at least 25% of the RDI in the recommended daily dose of vitamin D.

Product presentation must not imply or refer to any thyroid related diseases.

If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

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

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Product presentation must not imply or refer to serious immunological diseases.

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.

Product presentation must not imply or refer to chronic fatigue syndrome.

Product presentation must not imply or refer to lowering or raising blood sugar/glucose levels from outside of the normal healthy range.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

This medicine contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.

(If medicine contains one benzoate) Contains [insert name of benzoate] Or (If medicine contains two or more benzoates) Contains benzoates [or words to that effect].

Additional Product information

Pack Size/Poison information

Pack Size Poison Schedule

Components

1. Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

Amylase	111 DU
betacarotene	.923 mg
Biotin	75 microgram
Brassica oleracea var. capitata leaf Powder	1.38 mg
Brassica oleracea var. gemmifera leaf bud Powder	1.38 mg
Brassica oleracea var. italica sprout Extract dry concentrate	1.38 mg
Equivalent: Brassica oleracea var. italica (Dry)	414 mg
Brassica oleracea var. viridis leaf Powder	5.63 mg
calcified lithothamnion species	93.75 mg
Equivalent: magnesium	2.06 mg
Equivalent: calcium	30 mg
calcium ascorbate dihydrate	45.39 mg
Equivalent: calcium	4.27 mg
Equivalent: ascorbic acid	37.5 mg
calcium carbonate	226.26 mg
Equivalent: calcium	90.5 mg

calcium folinate138.89 microgramEquivalent: folinic acid100 microgramcalcium pantothenate2.73 mgEquivalent: pantothenic acid2.5 mgCarum carvi seed Extract dry concentrate2.5 mgEquivalent: Carum carvi (Dry)10 mgcellulase55 CU

 chromium nicotinate
 104.17 microgram

 Equivalent: chromium
 12.5 microgram

 colecalciferol
 .0012 mg

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copper gluconate	892.86 microgram
Equivalent: copper	125 microgram
cyanocobalamin	2.5 microgram
d-alpha-tocopheryl acid succinate	10.33 mg
Fucus vesiculosus whole plant Powder	12.5 mg
iron (II) glycinate	5.4785 mg
Equivalent: iron	1.5 mg
lipase	37 LipU
magnesium amino acid chelate	185.63 mg

Equivalent: magnesium 37.13 mg magnesium ascorbate monohydrate 13.93 mg

Equivalent: magnesium 862.21 microgram
Equivalent: ascorbic acid 12.5 mg
manganese amino acid chelate 1.25 mg
Equivalent: manganese 125 microgram

Mentha X piperita leaf Extract dry concentrate

Equivalent: Mentha X piperita (Dry) 10 mg
nicotinamide 5 mg

palm tocotrienols complex 96.5 microgram

Petroselinum crispum herb Powder 3.38 mg
phytomenadione 5 microgram

protease 3.066 Thousand HUT
pyridoxine hydrochloride 911.65 microgram
Equivalent: pyridoxine 750 microgram

retinol acetate86.25 microgramriboflavin750 microgramselenomethionine43.47 microgramEquivalent: selenium17.5 microgram

Spinacia oleracea leaf Powder 1.38 mg
Taraxacum officinale leaf Extract dry concentrate 3.38 mg

Equivalent: Taraxacum officinale (Dry)

thiamine hydrochloride

Equivalent: thiamine

Equivalent: thiamine

750 microgram

tilactase 69 ALU

zinc amino acid chelate 18.75 mg

Equivalent: zinc 3.75 mg

Zingiber officinale root Extract dry concentrate 2.5 mg

Equivalent: Zingiber officinale (Dry) 50 mg

Other Ingredients (Excipients)

Acacia

butylated hydroxytoluene

calcium hydrogen phosphate dihydrate

citric acid

colloidal anhydrous silica croscarmellose sodium

crospovidone

dextrin

dl-alpha-tocopherol ethylcellulose

Gelatin

glucose monohydrate

2.5 mg



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hypromellose
liquid paraffin
magnesium stearate
maize starch
maltodextrin
medium chain triglycerides
microcrystalline cellulose
Pea Starch
pregelatinised maize starch
purified water
silicon dioxide
sodium alginate
sodium benzoate
sucrose

tartaric acid

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Department of Health

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 327961 xEO Mega

ARTG entry for Medicine Listed

Sponsor doTERRA Australia Pty Ltd

Postal Address 102 / 271 Wellington Road, Mulgrave, VIC, 3170

Australia

ARTG Start Date 20/12/2019
Product Category Medicine
Status Active

Approval Area 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.

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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.

Products

1 . xEO Mega

Product Type Single Medicine Product Effective Date 24/02/2020

Permitted Indications

Antioxidant/Reduce free radicals formed in the body

Helps reduce/decrease free radical damage to body cells

Maintain/support eye health

Helps maintain/support eye retina health

Maintain/support healthy eyesight/vision

Maintain/support general health and wellbeing

Maintain/support bone health

Maintain/support bone strength

Help maintain/support bone mineralisation

Vitamin D helps calcium absorption (or words of like intent) and a diet deficient in calcium can lead to osteoporosis in later life

Maintain/support cardiovascular system health

Maintain/support healthy cardiovascular system function

Maintain/support heart health

Maintain/support immune system health

Maintain/support healthy immune system function

Maintain/support muscle function

Maintain/support healthy neuromuscular system/function

Maintain/support absorption of dietary (state vitamin/mineral/nutrient)

Maintain/support (state vitamin/mineral/nutrient) levels in the body

Maintain/support (state vitamin/mineral/nutrient) levels in the body when sun exposure is inadequate

Maintain/support (state vitamin/mineral/nutrient) levels in the body when sun exposure is inadequate in elderly individuals

Helps prevent dietary (state vitamin/mineral/nutrient) deficiency

Maintain/support brain function



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Therapeutic Goods Administration

Maintain/support wound healing

Indication Requirements

Product presentation must not imply or refer to serious immunological diseases.

Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

Product presentation must not imply or refer to serious cardiovascular conditions.

Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.

If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

Product presentation must not imply or refer to vision correction, faults or serious eye disease e.g. macular degeneration.

Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis. Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.

Product presentation must not imply or refer to mental illnesses, disorders or conditions.

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

Indication only for use for medicines that contain vitamin D as an active ingredient. The medicines may only contain a maximum recommended daily dose of 25 micrograms or less of vitamin D and as a minimum, also contain at least 25% of the RDI in the recommended daily dose of vitamin D.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

No Warnings included on Record

Additional Product information

Pack Size/Poison information

Pack Size Poison Schedule

Components

1 . Formulation 1

Dosage FormCapsule, soft

Route of Administration
Oral

Visual Identification

Active Ingredients

astaxanthin esters extracted from Haematococcus pluvialis

Equivalent: Astaxanthin (of Haematococcus pluvialis)

betacarotene

1.0009 mg

Borago officinalis seed Oil fixed

50 mg

Caraway Oil

Chamomile Oil German

colecalciferol

5 microgram

colecalciferol concentrated fish Omega-3 triglycerides 179.028 mg concentrated fish Omega-3 triglycerides 81 mg Equivalent: eicosapentaenoic acid 8.1 mg Equivalent: docosahexaenoic acid 40.5 ma **Cumin Oil** 3.429 mg d-alpha-tocopherol 10.1 mg **Ginger Oil** 2.856 mg lutein .75 ma lycopene .25 mg Olibanum Oil 4.572 mg Orange Oil 3.429 mg

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Peppermint Oil	3.429 mg
Punica granatum seed Oil fixed	12.5 mg
Syzygium aromaticum whole plant Oil essential	5.715 mg
Thyme Oil	3.999 mg
zeaxanthin	.2504 mg

Other Ingredients (Excipients)

d-alpha-tocopherol

dl-alpha-tocopherol

glycerol

lecithin

Maize Oi

mixed (low-alpha type) tocopherols concentrate

modified food starch

Olive Oil

purified water

Rosmarinus officinalis

Safflower Oil

Sunflower Oil

vegetable oil

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Department of Health

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 285193 Alpha CRS+

ARTG entry for Medicine Listed

Sponsor doTERRA Australia Pty Ltd

Postal Address 102 / 271 Wellington Road, Mulgrave, VIC, 3170

Australia

ARTG Start Date 3/02/2017

Product Category Medicine

Status Active

Approval Area 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+

Product Type Single Medicine Product Effective Date 8/07/2020

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

Pack Size Poison Schedule

Components

Department of Health

Therapeutic Goods Administration

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

A				
Active	ına	ırea	ıen	Its

acetyl levocarnitine hydrochloride	29.48 mg
alpha lipoic acid	25 mg
Boswellia serrata gum oleoresin Extract dry concentrate standardised	76.92 mg
Equivalent: Boswellia serrata (Dry)	461.54 mg
bromelains	4.17 mg
Camellia sinensis leaf Extract dry concentrate standardised	9.04 mg
Equivalent: Camellia sinensis (Dry)	271.2 mg
Carum carvi seed Extract dry concentrate	2.5 mg
Equivalent: Carum carvi (Dry)	10 mg
curcumin	7.89 mg
Ginkgo biloba leaf Extract dry concentrate standardised	200 microgram
Equivalent: Ginkgo biloba (Dry)	10 mg
Mentha X piperita leaf Extract dry concentrate	2.5 mg
Equivalent: Mentha X piperita (Dry)	10 mg
Pinus pinaster	2.61 mg

Punica granatum seed Extract dry concentrate
Equivalent: Punica granatum (Dry)

quercetin dihydrate

Reynoutria japonica root Extract dry concentrate standardised

Equivalent: Reynoutria japonica (Dry)

Scutellaria baicalensis root Extract dry concentrate

Equivalent: Scutellaria baicalensis (Dry)

Sesamum indicum seed Extract dry concentrate

Equivalent: Sesamum indicum (Dry)

Vitis vinifera seed Extract dry concentrate standardised

Silybum marianum fruit Extract dry concentrate standardised Equivalent: Silybum marianum (Dry) ubidecarenone

Equivalent: Vitis vinifera (Dry)

Zingiber officinale root Extract dry concentrate

Equivalent: Zingiber officinale (Dry)

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

15.63 mg

781.25 mg

12.5 mg

25 mg

2.5 g

5 mg

20 mg

31.25 mg

2.1875 g

12.5 mg

5.2632 mg

631.58 mg

2.5 mg

50 mg

44.12 mg

573.53 mg



Department of Health

Therapeutic Goods Administration

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