



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	344322	Sangreal
ARTG entry for	Medicine Listed	
Sponsor	Greal Labs Pty Ltd	
Postal Address	PO Box 193, Fitzroy, VIC, 3065 Australia	
ARTG Start Date	24/09/2020	
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 . Sangreal

Product Type	Single Medicine Product	Effective Date	24/09/2020
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Permitted Indications

Antioxidant/Reduce free radicals formed in the body
Helps reduce/decrease free radical damage to body cells
Maintain/support energy levels
Maintain/support energy production
Maintain/support general health and wellbeing
Maintain/support blood health
Maintain/support healthy thyroid gland function
Maintain/support healthy thyroid hormones
Maintain/support immune system health
Maintain/support healthy immune system function
Aid/assist/helps glucose/sugar/carbohydrate metabolism
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)
Maintain/support nervous system health
Maintain/support nervous system function
Maintain/support skin health

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.

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.



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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 lowering or raising blood sugar/glucose levels from outside of the normal healthy range.

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

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

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

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

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.

If you are pregnant, or considering becoming pregnant, do not take vitamin A supplements without consulting your doctor or pharmacist.

Adults only.

WARNING - When taken in excess of 3000 micrograms retinol equivalents, vitamin A can cause birth defects.

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.

Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

ascorbic acid	100 mg
betacarotene	2.01 mg
Biotin	50 microgram
borax	13.23 mg
Equivalent: boron	1.5 mg
calcium folinate	325.52 microgram
Equivalent: folic acid	300 microgram
calcium pantothenate	16.38 mg
Equivalent: pantothenic acid	15 mg
choline bitartrate	60.17 mg
Equivalent: choline	25 mg
Citrus bioflavonoids extract	25 mg
colecalfiferol	.025 mg
hydroxocobalamin	150 microgram
levomefolate calcium	108.4 microgram
Equivalent: levomefolic acid	100 microgram
lutein	7 mg
manganese gluconate	8.1 mg
Equivalent: manganese	1 mg
mecobalamin (co-methylcobalamin)	50 microgram

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menaquinone 7	90 microgram
mixed (low-alpha type) tocopherols concentrate	25.002 mg
molybdenum trioxide	187.54 microgram
Equivalent: molybdenum	125 microgram
nicotinamide	50 mg
phytomenadione	.07 mg
potassium iodide	261.6 microgram
Equivalent: iodine	200 microgram
pyridoxal 5-phosphate monohydrate	12.54 mg
Equivalent: pyridoxine	8 mg
retinol palmitate	551 microgram
Equivalent: vitamin A	301 RE/microgram
riboflavin sodium phosphate	1.32 mg
Equivalent: riboflavin	1 mg
selenomethionine	186.3 microgram
Equivalent: selenium	75 microgram
thiamine hydrochloride	2.54 mg
Equivalent: thiamine	2 mg
zeaxanthin	.4 mg
zinc citrate dihydrate	46.73 mg
Equivalent: zinc	15 mg

Other Ingredients (Excipients)

Acacia
ascorbyl palmitate
beta-tocopherol
butylated hydroxytoluene
colloidal anhydrous silica
d-alpha-tocopherol
delta-tocopherol
disodium edetate
dl-alpha-tocopherol
fractionated coconut oil
gamma-tocopherol
gellan gum
hypromellose
liquid glucose
maize starch
maltodextrin
microcrystalline cellulose
Pea Starch
potable water
potassium acetate
purified water
silicon dioxide
sodium alginate
sodium ascorbate
starch sodium octenyl succinate
sucrose
tapioca starch

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