



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	430730	Bloom
ARTG entry for	Medicine Listed	
Sponsor	Greal Labs Pty Ltd	
Postal Address	PO Box 193, Fitzroy, VIC, 3065 Australia	
ARTG Start Date	12/12/2023	
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.

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 . Bloom

Product Type	Single Medicine Product	Effective Date	12/12/2023
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Permitted Indications

- Maintain/support energy levels
- Helps convert (state food) into energy
- Maintain/support body metabolism/metabolic rate
- Maintain/support healthy eye function
- Maintain/support eye health
- Maintain/support healthy eyesight/vision
- Maintain/support healthy growth and development
- Maintain/support general health and wellbeing
- Maintain/support general health and wellbeing
- Aids/assists teeth development
- Maintain/support healthy teeth
- Aids/assists healthy bone development/growth/building
- Maintain/support bone strength
- 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 healthy immune system function
- Maintain/support immune system to fight illness
- Aid/assist/helps glucose/sugar/carbohydrate metabolism
- Maintain/support absorption of dietary (state vitamin/mineral/nutrient)
- Maintain/support (state vitamin/mineral/nutrient) levels in the body
- Maintain/support cognitive function/mental function
- Maintain/support brain function
- Maintain/support nerve conduction
- Aid/assist/helps synthesis of neurotransmitters
- Maintain/support skin health
- Maintain/support skin integrity/structure
- Maintain/support skin regeneration

Public Summary



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

Maintain/support wound healing

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.

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.

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

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 serious immunological diseases.

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

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

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

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).

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.

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).

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.

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form	Tablet, chewable
Route of Administration	Oral

Visual Identification

Active Ingredients

betacarotene	300 microgram
Biotin	10 microgram
borax	4.41 mg
Equivalent: boron	500 microgram
calcium ascorbate dihydrate	60.86 mg
Equivalent: ascorbic acid	50 mg
calcium folinate	108.5 microgram
Equivalent: folic acid	100 microgram
calcium pantothenate	5.46 mg
Equivalent: pantothenic acid	5 mg
calcium phosphate	154.83 mg
Equivalent: calcium	60 mg
choline bitartrate	24.31 mg
Equivalent: choline	10 mg

Public Summary



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Citrus bioflavonoids extract	10 mg
colecalfiferol	.0085 mg
ferrous fumarate	9.13 mg
Equivalent: iron	3 mg
glycine	150 mg
hydroxocobalamin	20 microgram
inositol	25 mg
levomefolate glucosamine	89 microgram
Equivalent: levomefolic acid	50 microgram
lysine hydrochloride	25 mg
Equivalent: lysine	20 mg
magnesium phosphate pentahydrate	242.01 mg
Equivalent: magnesium	50 mg
manganese gluconate	2.43 mg
Equivalent: manganese	300 microgram
mecobalamin	10 microgram
menaquinone 7	22.5 microgram
mixed (low-alpha type) tocopherols concentrate	3 mg
molybdenum trioxide	30 microgram
Equivalent: molybdenum	20 microgram
nicotinamide	6 mg
phytomenadione	1 microgram
potassium iodide	65.4 microgram
Equivalent: iodine	50 microgram
pyridoxal 5-phosphate monohydrate	1.56 mg
Equivalent: pyridoxine	1 mg
retinol palmitate	276.375 microgram
Equivalent: vitamin A	150 RE/microgram
riboflavin sodium phosphate	657.9 microgram
Equivalent: riboflavin	500 microgram
selenomethionine	49.7 microgram
Equivalent: selenium	20 microgram
Tagetes erecta flower Extract dry concentrate	4 mg
Equivalent: Tagetes erecta (Fresh)	2200 mg
taurine	25 mg
thiamine hydrochloride	500 microgram
Equivalent: thiamine	393.4 microgram
zinc glycinate	16.33 mg
Equivalent: zinc	5 mg

Other Ingredients (Excipients)

Acacia
butylated hydroxytoluene
citric acid
colloidal anhydrous silica
d-alpha-tocopherol
dl-alpha-tocopherol
Flavour
fractionated coconut oil
hypromellose
liquid glucose
magnesium stearate

Public Summary



Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

maize starch
maltodextrin
mixed (low-alpha type) tocopherols concentrate
modified food starch
silicon dioxide
Siraitia grosvenorii
sodium ascorbate
starch sodium octenyl succinate
sucrose
tapioca starch
xylitol

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Public Summary