



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	334494	Vitality X + Collagen
ARTG entry for	Medicine Listed	
Sponsor	JSHealth Vitamins Pty Ltd	
Postal Address	17 Kimberley Street, Vaucluse, NSW, 2030 Australia	
ARTG Start Date	17/04/2020	
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 . Vitality X + Collagen

Product Type	Single Medicine Product	Effective Date	17/04/2020
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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 collagen formation
Maintain/support collagen health
Maintain/support energy production
Maintain/support vitality
Maintain/support general health and wellbeing
Maintain/support connective tissue health
Aid/assist/helps connective tissue production/formation
Maintain/support bone health
Helps maintain/supports healthy joint cartilage growth/development/production
Maintain/support blood capillary health
Decrease/reduce/relieve flatulence/carminative
Decrease/reduce/relieve symptoms of indigestion/dyspepsia
Relieve digestive discomfort
Hepatoprotectant/protect the liver
Maintain/support liver health
Maintain/support immune system health
Maintain/support healthy immune system function
Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)
Aid/assist/helps synthesis of neurotransmitters
Maintain/support skin firmness
Maintain/support skin health

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Maintain/support skin hydration in females
 Maintain/support skin elasticity in females
 Maintain/support skin integrity/structure
 Maintain/support wound healing

Indication Requirements

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

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 liver disease, such as cirrhosis, hepatitis.

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

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

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

Product presentation must not encourage excessive or harmful consumption of alcohol or other toxic substances.

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).

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 any form of arthritis or osteoarthritis unless qualified as mild.

Product presentation must not imply or refer to gastro oesophageal reflux disease.

Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.

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
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Components

1 . Formulation 1

Dosage Form	Powder, oral
Route of Administration	Oral

Visual Identification

Active Ingredients

Aloe vera leaf inner juice Powder	8.34 mg/g
Equivalent: Aloe vera (Fresh)	1.668 g/g
ascorbic acid	33.33 mg/g
astaxanthin esters extracted from Haematococcus pluvialis	13.33 mg/g
Equivalent: Astaxanthin (of Haematococcus pluvialis)	.6665 mg/g
colloidal anhydrous silica	53.48 mg/g
Equivalent: silicon	25 mg/g
Curcuma longa rhizome Extract dry concentrate	13.34 mg/g
Equivalent: Curcuma longa (Dry)	266.8 mg/g
d-alpha-tocopheryl acid succinate	6.89 mg/g
Eleutherococcus senticosus root Extract dry concentrate	5.56 mg/g
Equivalent: Eleutherococcus senticosus (Dry)	83.4 mg/g
glutamine	125 mg/g
glycine	83.34 mg/g

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hydrolysed collagen	500 mg/g
quercetin dihydrate	16.66 mg/g
Vaccinium myrtillus fruit Powder	16.66 mg/g

Other Ingredients (Excipients)

colloidal anhydrous silica
Flavour
malic acid
maltodextrin
Stevia rebaudiana

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