

### **Australian Government**

## Department of Health and Aged Care

Therapeutic Goods Administration

#### **Public Summary**

Summary for ARTG Entry: Vitality X + Collagen 334494

ARTG entry for Medicine Listed

Sponsor JSHealth Vitamins Pty Ltd

**Postal Address** 31 Knox Street, Double Bay, Sydney, NSW, 2028

17/04/2020 ARTG Start Date **Product Category** Medicine Status Active

Listed Medicines Approval Area

#### 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 . Vitality X + Collagen

**Product Type** Effective Date 21/07/2023 Single Medicine Product

## **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 in females

Maintain/support skin health

Maintain/support skin hydration in females

Maintain/support skin elasticity in females

Maintain/support skin integrity/structure

Maintain/support wound healing

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#### **Indication Requirements**

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

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

Product presentation must not imply or refer to liver disease, such as cirrhosis, hepatitis.

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

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

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 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

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

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 chronic fatigue syndrome.

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

No Warnings included on Record

### **Additional Product information**

## Pack Size/Poison information

Pack Size Poison Schedule

## 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
hydrolysed collagen	500 mg/g
quercetin dihydrate	16.66 mg/g
Vaccinium myrtillus fruit Powder	16.66 mg/g
Other Ingredients (Excipients)	

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colloidal anhydrous silica Flavour malic acid maltodextrin Stevia rebaudiana

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