### **Australian Government**

## **Department of Health and Aged Care**

Therapeutic Goods Administration

### **Public Summary**

Summary for ARTG Entry: 396773 Oxyguard

ARTG entry for Medicine Listed

Sponsor Biomedica Nutraceuticals Pty Ltd

Postal Address PO Box 7052, ALEXANDRIA, NSW, 2015

Australia

ARTG Start Date 30/09/2022

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. Oxyguard

Product Type Single Medicine Product Effective Date 10/02/2023

## 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 general health and wellbeing

Maintain/support gum health

Maintain/support connective tissue health

Aid/assist/helps connective tissue production/formation

Maintain/support bone health

Aids/assists healthy bone development/growth/building

Helps maintain/supports healthy joint cartilage growth/development/production

Helps maintain/support joint cartilage health

Helps maintain/support healthy cholesterol

Maintain/support cardiovascular system health

Maintain/support healthy cardiovascular system function

Maintain/support blood capillary health

Maintain/support blood vessel health

Maintain/support immune system health

Maintain/support healthy immune system function

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

Maintain/support wound healing

Maintain/support skin repair/healing/regeneration

## Indication Requirements

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 serious cardiovascular conditions.

### Page 1 of 3



### **Australian Government**

## **Department of Health and Aged Care**

Therapeutic Goods Administration

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 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).

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

Product presentation must not imply or refer to lowering or raising blood cholesterol 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

The recommended dose of this medicine provides small amounts of caffeine

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

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			
ascorbic acid			120 mg
betacarotene			3 mg
Camellia sinensis leaf Extract dry concentrate standardised			50 mg
Equivalent: Camellia sinensis (Dry)			1.5 g
Curcuma longa rhizome Extract dry concentrate			30 mg
Equivalent: Curcuma longa (Dry)			300 mg
cysteine hydrochloride monohydrate			50 mg
Equivalent: cysteine			34.5 mg
d-alpha-tocopheryl acid succinate			82.64 mg
Equivalent: d-alpha-tocopherol			100 IU
Ginkgo biloba leaf Extract dry concentrate			6 mg
Equivalent: Ginkgo biloba (Dry)			300 mg
glutamine			50 mg
glycine			50 mg
mixed (low-alpha type) tocopherols concentrate			5.001 mg

Page 2 of 3

rutoside

selenomethionine

Equivalent: selenium

Produced at 05.01.2024 at 04:08:18 AEDT

50 mg

100 mg

125 microgram

50 microgram

11.43 mg

800 mg

100 mg

4.167 mg

1 mg

5 g

Silybum marianum fruit Extract dry concentrate

Vaccinium myrtillus fruit Extract dry concentrate

Equivalent: Reynoutria japonica (Dry)

Equivalent: Silybum marianum (Dry)

Equivalent: Vaccinium myrtillus (Fresh)

Vitis vinifera seed Extract dry concentrate

Reynoutria japonica root Extract dry concentrate standardised



# **Australian Government**

## **Department of Health and Aged Care**

Therapeutic Goods Administration

Equivalent: Vitis vinifera (Dry) 500 mg

zinc citrate dihydrate 15.58 mg

Equivalent: zinc 5 mg

#### Other Ingredients (Excipients)

Acacia

colloidal anhydrous silica

hypromellose

maltodextrin

microcrystalline cellulose

Pea Starch

potable water

purified water

silicon dioxide

sodium alginate sodium starch glycollate

Soya Oil

stearic acid

<sup>©</sup> Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at http://www.tga.gov.au/about/website-copyright.htm.