

# **Australian Government**

## **Department of Health**

# Therapeutic Goods Administration

#### **Public Summary**

Summary for ARTG Entry: 346043 SynQ10

ARTG entry for Medicine Listed

Sponsor Biomedica Nutraceuticals Pty Ltd

Postal Address PO Box 7052, ALEXANDRIA, NSW, 2015

Australia

ARTG Start Date 16/10/2020
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.

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 . SynQ10

Product Type Single Medicine Product Effective Date 9/11/2020

#### **Permitted Indications**

Antioxidant/Reduce free radicals formed in the body

Maintain/support energy production

Maintain/support general health and wellbeing

Maintain/support cardiovascular system health

## **Indication Requirements**

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

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.

# Standard Indications

No Standard Indications included on Record

## **Specific Indications**

No Specific Indications included on Record

# Warnings

Do not take while on warfarin therapy without medical advice.

#### **Additional Product information**

# Pack Size/Poison information

Pack Size Poison Schedule

#### Components

1 . Formulation 1

Dosage Form Capsule, soft Route of Administration Oral

Visual Identification

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Active Ingredients	
ubidecarenone	120 mg
ubiquinol-10	30 mg
Other Ingredients (Excipients)	
chlorophyllin-copper complex	
d-alpha-tocopherol	
Gelatin	
glycerol	
hydrogenated vegetable oil	
lecithin	
purified water	
Rice bran oil	
Sunflower Oil	

yellow beeswax

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