# **Australian Government**

### **Department of Health**

## Therapeutic Goods Administration

#### **Public Summary**

Summary for ARTG Entry: 228742 Ubiquinol 100mg

ARTG entry for Medicine Listed

Sponsor Herbs of Gold Pty Ltd

Postal Address PO Box 3143, KIRRAWEE, NSW, 2232

Australia

ARTG Start Date 1/10/2014
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. Ubiquinol 100mg

**Product Type** Single Medicine Product **Effective Date** 5/05/2022

### **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

Maintain/support healthy cardiovascular system function

Maintain/support heart health

Maintain/support (state vitamin/mineral/nutrient) levels in the body

Maintain/support semen health

Maintain/support sperm health

Maintain/support sperm motility

### **Indication Requirements**

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

Product presentation must not imply or refer to infertility.

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.

#### **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**

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Pack Size/Poison information

Pack Size Poison Schedule

Components

1 . Formulation 1

Dosage Form Capsule, soft

Route of Administration Oral

**Visual Identification** 

**Active Ingredients** 

ubiquinol-10 100 mg

Other Ingredients (Excipients)

Gelatin

glycerol

iron oxide black

lecithin

purified water

Rice bran oil yellow beeswax

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