



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	203744	Ubiquinol BioActive 100mg
ARTG entry for	Medicine Listed	
Sponsor	FIT-BioCeuticals Pty Ltd	
Postal Address	Care of Blackmores Ltd PO Box 1725, Warriewood, NSW, 2102 Australia	
ARTG Start Date	6/12/2012	
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 BioActive 100mg

Product Type	Single Medicine Product	Effective Date	20/02/2021
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Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Antioxidant/Reduce free radicals formed in the body in aging individuals
- Maintain/support energy levels
- Maintain/support energy production
- Maintain/support general health and wellbeing in aging individuals
- Maintain/support general health and wellbeing
- Helps in the maintenance of healthy blood lipids/blood fats
- Helps maintain/support healthy cholesterol
- Maintain/support cardiovascular system health
- Maintain/support healthy cardiovascular system function
- Maintain/support heart health
- Maintain/support blood vessel health
- Maintain/support (state vitamin/mineral/nutrient) levels in the body
- Maintain/support (state vitamin/mineral/nutrient) levels in the body in aging individuals

Indication Requirements

- Product presentation must not imply or refer to lowering blood lipids, blood fats and triglycerides.
- 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).
- Product presentation must not imply or refer to lowering or raising blood cholesterol levels from outside of the normal healthy range
- 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.
- 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 serious cardiovascular conditions.

Standard Indications

No Standard Indications included on Record

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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
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Components

1 . Formulation 1

Dosage Form Capsule, soft

Route of Administration Oral

Visual Identification

Active Ingredients

ubiquinol-10	100 mg
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Other Ingredients (Excipients)

caramel

dl-alpha-tocopherol

Gelatin

glycerol

lecithin

Linseed Oil

purified water

yellow beeswax

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