



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 203744 Ubiquinol BioActive 100mg

ARTG entry for Medicine Listed
Sponsor FIT-BioCeuticals Limited
Postal Address PO Box 6454, ALEXANDRIA, NSW, 2015
 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.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

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	7/06/2018
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Permitted Indications

Indication Requirements

No Indication Requirements included on Record

Standard Indications

May help reduce the oxidation of LDL cholesterol.

Specific Indications

- [1] Supports the maintenance of healthy ubiquinol levels.
- [2a] Ubiquinol may be of particular benefit to people experiencing increased oxidative stress as occurs with normal healthy advancing/increasing age/ing.
- [2b] Ubiquinol supplementation may be supportive/beneficial for the middle-aged to elderly (to help combat oxidation associated with increasing age).
- [3] Ubiquinol supports healthy energy synthesis.
- [4a] Ubiquinol supports healthy antioxidant activity, including the regeneration of vitamin E.
- [4b] Ubiquinol is a lipid-soluble antioxidant at physiological concentrations.
- [5a] Ubiquinol is absorbed at a faster and more concentrated rate than ubiquinone, so that the plasma concentration of ubiquinol is higher and is reached much sooner than when taking ubiquinone.
- [5b] Ubiquinol markedly slows the rate of LDL peroxidation, providing strong protection for lipoproteins/against free radicals.
- [5c] Ubiquinol serves as a/n potent/effective antioxidant in mitochondria, lipid membranes and plasma lipoproteins, and is also a regenerator of other lipid-soluble antioxidants (vitamin E), as well as ubiquinone and vitamin C.
- [6a] Ubiquinol has superior absorption / has a statistically higher absorption rate / higher bioavailability / is more bioavailable than ubiquinone.
- [6b] Ubiquinol is absorbed at a faster and more concentrated rate than ubiquinone, so that the plasma concentration of ubiquinol is higher and is reached much sooner than when taking ubiquinone.
- [7a] Ubiquinol supplementation / Supplementation with ubiquinol increases CoQ10:cholesterol ratio in the blood.
- [7b] Increases total and reduced blood CoQ10.
- [8a] Ubiquinol modulates gene expression which results in reduced low density lipoprotein cholesterol levels in healthy people.
- [8b] Ubiquinol may help to reduce low density lipoprotein cholesterol levels in healthy people.
- [9] Ubiquinol reduces the expression of (DNA methylation of) the pro-inflammatory chemokine ligand 2 gene. / of a pro-inflammatory gene. / Ubiquinol reduces/modulates pro-inflammatory gene expression.

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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

Active Ingredients

ubiquinol-10

100 mg

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