

Coenzyme Q10

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Coenzyme Q10 (UBIQUINONE-10) (PDF Version - 36 K) This monograph is intended to serve as a guide to industry for the preparation of Product Licence Applications (PLA) and labels for natural health product market authorization. It is not intended to be a comprehensive review of the medicinal ingredient. Notes Text in parentheses is additional optional information which can be included on the label at the applicant's discretion. The solidus (/) indicates that the terms and/or statements are synonymous. Either term or statement may be selected by the applicant on the label. Date January 31, 2025 Proper name(s), Common name(s), Source information Table 1. Proper name(s), Common name(s), Source information Proper name(s) Common name(s) Source information Source ingredient(s) Source material(s) Part(s) Preparation(s) 2,5-Cyclohexadiene-1,4-dione, 2-[(2E,6E,10E,14E,18E,22E,26E,30E,34E)-3,7,11,15,19,23,27,31,35,39-decamethyl-2,6,10,14,18,22,26,30,34,38-tetracontadecaenyl]-5,6-dimethoxy-3-methyl Coenzyme Q10 CoQ10 Ubidecarenone Ubiquinone-10 N/A Agrobacterium rhizogenes Agrobacterium tumefaciens Aspergillus clavatus Escherichia coli Gluconobacter suboxydans Leucosporidium scottii Paracoccus denitrificans Rhodobacter sphaeroides Rhodospirillum rubrum Saccharomyces cerevisiae Schizosaccharomyces pombe Whole Biosynthesis Coenzyme Q10 N/A N/A Synthetic References: Proper name: USP-NF 2024; Common names: Brayfield and Cadart 2024; RSC 2024; USP-NF 2024; Storch et al. 2007; Park et al. 2005; Source information: Lipshutz et al. 2005; Kawamukai 2002; Lipshutz et al. 2002; Szkopinska 2000; Yoshida et al. 1998; Zhao et al. 1997. Route of administration Oral Dosage form(s) This monograph excludes foods or food-like dosage forms as indicated in the Compendium of Monographs Guidance Document. Acceptable dosage forms for oral use are indicated in the dosage form drop-down list of the web-based Product Licence Application form for Compendial applications. Use(s) or Purpose(s) Helps to maintain and/or support cardiovascular health (Rosenfeldt et al. 2007; Baggio et al. 1994; Langsjoen et al. 1988). Helps to reduce the frequency of migraine headaches and associated nausea and vomiting when taken as a prophylactic/preventative (Hershey et al. 2007; Sandor et al. 2005; Rozen et al. 2002). Source of (an) antioxidant(s)/Provides (an) antioxidant(s) (Kalpravidh et al. 2005; Rosenfeldt et al. 2005; Crane 2001; Chello et al. 1994). Source of (an) antioxidant(s)/Provides (an) antioxidant(s) that help(s) fight/protect (cell) against/reduce (the oxidative effect of/the oxidative damage caused by/cell damage caused by) free radicals (Kalpravidh et al. 2005; Rosenfeldt et al. 2005; Crane 2001; Chello et al. 1994). Notes: The above uses can be combined on the product label (e.g., Helps to maintain and support cardiovascular health and to reduce the frequency of migraine headaches and associated nausea and vomiting when taken as a preventative). The terms 'Helps' or 'Helps to' can be used interchangeably on the label. If Coenzyme Q10 is combined with other medicinal ingredients with antioxidant properties, there is an option to use the antioxidant claims in plural. The singular should be used when the product only contains one chemical substance (e.g., Coenzyme Q10) as the medicinal ingredient associated with the antioxidant claim. Dose(s) Subpopulation(s) Adults 18 years and older Quantity(ies) Antioxidant Not to exceed 300 milligrams of Coenzyme Q10, per day (Bonakdar and Guarneri 2005; Kalpravidh et al. 2005; Rosenfeldt et al. 2005; Chello et al. 1994; Langsjoen 1994; Langsjoen et al. 1988; Tanaka et al. 1982) Cardiovascular health 30 - 300 milligrams of Coenzyme Q10, per day (Bonakdar and Guarneri 2005; Kalpravidh et al. 2005; Rosenfeldt et al. 2005; Chello et al. 1994; Langsjoen 1994; Langsjoen et al. 1988; Tanaka et al. 1982) Migraine prophylaxis 150 - 300 milligrams of Coenzyme Q10, per day (Sandor et al. 2005; Rozen et al. 2002) Direction(s) for use No statement required Duration(s) of use Migraine prophylaxis/prevention Use for at least 3 months to see beneficial effects (Hershey et al. 2007; Sandor et al. 2005; Rozen et al. 2002). Other uses No statement required. Risk information Caution(s) and warning(s) All products Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are pregnant or breastfeeding. Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are taking blood pressure medication (Rosenfeldt et al. 2007; Singh et al. 1999). Products providing more than 100 mg of Coenzyme Q10 per day Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are taking blood thinners (Engelsen et al. 2003; Landbo and Almdal 1998; Spigset 1994). Migraine prophylaxis/prevention Ask a health care practitioner/health care provider/health care professional/doctor/physician if migraine frequency

increases and associated nausea and vomiting persist or worsen. Contraindication(s) No statement required. Known adverse reaction(s) No statement required. Non-medicinal ingredients Must be chosen from the current Natural Health Products Ingredients Database (NHPID) and must meet the limitations outlined in the database. Storage conditions Must be established in accordance with the requirements described in the Natural Health Products Regulations . Specifications The finished product specifications must be established in accordance with the requirements described in the Natural and Non-prescription Health Products Directorate (NNHPD) Quality of Natural Health Products Guide. The medicinal ingredient must comply with the requirements outlined in the NHPID. Example Of Product Facts: Consult the Guidance Document, Labelling of Natural Health Products for more details. References cited Baggio E, Gandini R, Plancher AC, Passeri M, Carmosino G. 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DOSAGE FORM(S)

Acceptable dosage forms for oral use are indicated in the dosage form drop-down list of the web-based Product Licence Application form for Compendial applications.

RISK INFORMATION

Caution(s) and warning(s) All products Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are pregnant or breastfeeding. Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are taking blood pressure medication (Rosenfeldt et al. 2007; Singh et al. 1999). Products providing more than 100 mg of Coenzyme Q10 per day Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are taking blood thinners (Engelsen et al. 2003; Landbo and Almdal 1998; Spigset 1994). Migraine prophylaxis/prevention Ask a health care practitioner/health care provider/health care professional/doctor/physician if migraine frequency increases and associated nausea and vomiting persist or worsen. Contraindication(s) No statement required. Known adverse reaction(s) No statement required.

NON-MEDICINAL INGREDIENTS

Must be chosen from the currentNatural Health Products Ingredients Database (NHPID)and must meet the limitations outlined in the database.

STORAGE CONDITION(S)

Must be established in accordance with the requirements described in theNatural Health Products Regulations.

SPECIFICATIONS

The finished product specifications must be established in accordance with the requirements described in the Natural and Non-prescription Health Products Directorate (NNHPD) Quality of Natural Health Products Guide.The medicinal ingredient must comply with the requirements outlined in the NHPID.

	Common name(s)	Source information		
	Source material(s)	Part(s)	Preparation(s)	
1,4-dione, 2-[(2E,6E,10E)-2,6,10-trimethyl-3,7,11,15-tetradecanone]-3,5,9,13,17,19,23,27,31,35,39-decamethyl-2,6,10,14,18,22,26,30,34,38-decahydro-1H-benzo[1,2-b:4,5-b']dipyrrolo[3,2-d:2',3'-d']indole-1,3-dione	N/A	N/A	Synthetic	